PTSD Treatment for Incarcerated Men and Women: NIMH
NCT05168267
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Title: PTSD treatment for incarcerated men and women

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Background and Significance

Prisons and jails are the de facto largest providers of mental health services in the U.S. Mental illness is epidemic within the U.S. jail and prison population. It is estimated that over half of the 2.3 million people incarcerated in this country have experienced symptoms of mental illness within the past year[2]. The failure to effectively treat mental illness in incarcerated individuals is associated with a host of dire outcomes. Mental illness among incarcerated people is associated with higher rates of suicide; higher rates of victimization for rape and other forms of abuse; higher rates of rules infractions and solitary confinement; higher rates of violence; higher rates of substance abuse; and higher rates of recidivism and re-arrest after release [2]. Improving psychiatric care would thus yield substantial societal benefit in terms of reduced costs to the criminal justice system and increased public safety.

There is a particular need for more effective treatments for post-traumatic stress disorder (PTSD) within the incarcerated population. The prevalence of trauma history and PTSD are markedly higher in jail and prison populations than in the general population, with estimates of current PTSD prevalence among incarcerated individuals exceeding 20% [3,4], as opposed to 3-6% in the general population [5–7]. The prevalence of PTSD among incarcerated populations is at least as high as that of military veterans [8]. PTSD is also associated with an increased risk for crime-related behaviors, such as violence [9–11] and substance abuse [12,13]. There is virtually no research examining the efficacy of empirically supported therapies for PTSD in incarcerated individuals. Despite the patent need for more effective treatment strategies, there is scant translational research on PTSD in this population [14,15], and no randomized controlled studies that have tested the efficacy of empirically supported PTSD treatments in the prison setting. The treatment programs offered to people in prison (across the United States, but particularly in Wisconsin) target specific, overt criminal behaviors (e.g., alcohol/drug use, violence, sexual offenses), rather than underlying psychopathology. Our program of research could usher a new paradigm of–rehabilitation, by addressing the traumatic experiences and consequent psychopathology that predispose individuals to certain forms of maladaptive and criminal behavior.

Cognitive Processing Therapy (CPT) is a potentially promising PTSD treatment for the prison setting, primarily due to its cost- and time-effectiveness in the manualized group format. Individual (one-on-one) therapies such as Prolonged Exposure and Eye Movement Desensitization and Reprocessing are less likely to gain widespread implementation in prison systems, where therapist access is a major limitation. In addition, CPT is applicable to a wide range of individuals, such as those with minimal formal education, low IQs, or comorbid psychiatric disorders [16] . In studies of non-incarcerated individuals, CPT has been found to be more effective than wait-list control and equivalent to Prolonged Exposure [17–19]. The majority of non-incarcerated individuals undergoing CPT for PTSD exhibit a clinically significant reduction in symptoms, with over 40% achieving a loss of the diagnosis [20]. However, the generalizability of these findings to the offender population has not yet been determined. Our research study will determine whether CPT is indeed an effective and feasible treatment for PTSD in incarcerated people or whether different treatment strategies need to be developed.

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This project capitalizes on an extraordinary long-term collaboration between the University of Wisconsin-Madison and the State of Wisconsin Department of Corrections (DOC). Having facilitated University of Wisconsin-Madison investigators' basic research in forensic psychology for over 30 years, the DOC is eager to facilitate the translation to more effective therapies for people in prison. Prisons are an excellent environment for PTSD research because the percentage of prisoners with PTSD is extremely high, the need for treatment is easily justified, and the affected individuals are regularly available and willing to participate. The DOC has enabled our research team to collect data for our ongoing research projects with remarkable efficiency. Over the last 8 years, we have enrolled over 2,800 people incarcerated in the Wisconsin DOC into our research studies. Each of these individuals has participated in an in-person interview assessment with our research staff. We thus clearly have a one-of-a-kind research environment and a unique opportunity to advance research on PTSD in prison.

This study will be split into two branches: the NIMH branch, which corresponds to an R34 grant and the WPP branch, which corresponds to a grant from the Wisconsin Partnership Program. The two branches will follow similar protocols with minor differences in study objectives, research design, participant numbers, and assessments (described below). The NIMH branch will be implemented first. Once the NIMH branch has been completed at a specific facility, the WPP branch can be implemented at that facility.

Overall Study Objectives:
The branches of this study have both overlapping and complementary, unique primary objectives.

NIMH Branch:

1. Establish the feasibility of group CPT delivery in male and female incarcerated populations with PTSD.
2. Establish the acceptability of group CPT in male and female incarcerated populations with PTSD.
3. Establish feasibility of assessment collection for primary outcome measures, secondary outcome measures, and potential mediators and moderators during a clinical trial examining group CPT delivery in incarcerated settings.

WPP Branch:

1. Determine the effectiveness of group CPT in reducing PTSD symptom severity in male and female incarcerated populations.
2. Identify putative psychological mechanisms of response to CPT through pre-, mid-, and post-intervention measures of PTSD severity as well as measures of hopelessness, self-blame, and negative self-related thoughts.

Hypotheses:

NIMH Branch:

1. It is predicted that feasibility will be established by obtaining ≥80% participant retention for the CPT course. As additional metrics of feasibility we will assess eligibility;

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participation; compliance; adherence; competence; and safety.
2. It is predicted that group CPT acceptability will be established by obtaining mean scores ≥ 27 on the CSQ-8.
3. It is predicted that assessment collection feasibility will be established by obtaining 100% of PCL-5s at each timepoint for participants retained at that timepoint.

WPP Branch:
1. It is predicted that compared to the active control group, the CPT group will exhibit significantly greater reductions in PTSD symptom severity (primary outcome measure) as well as reductions in the severity of depression and general anxiety symptoms (secondary outcome measures) over the course of treatment.
2. It is predicted that the CPT group will exhibit greater reductions in hopelessness, self-blame, and negative self-related thoughts compared to the active control group.
    a. Within only the CPT group, the reductions in hopelessness, self-blame, and negative self-related thoughts will precede the reduction in PTSD symptoms.
    b. Within only the CPT group, the reduction in PTSD symptom severity will be mediated by reductions in hopelessness, self-blame, and negative self-related thoughts.

Trainee Project:
This study is part of the dissertation project of Odile Rodrik.

Participants:
Participants will be adult male and female individuals incarcerated in Wisconsin state prisons. Males will be recruited from Oakhill Correctional Institution (OCI), a minimum-security Wisconsin DOC facility housing over 600 adult males and Fox Lake Correctional Institution (FLCI), a medium-security Wisconsin DOC facility housing over 1,300 adult males. Females will be recruited from Taycheedah Correctional Institution (TCI), a mixed-security Wisconsin DOC facility housing over 800 adult females.

Participants will be withdrawn from the study if they exhibit disruptive behavior (e.g., verbal or physical abuse towards another participant or therapist, repeatedly do not respect group rules outlined at the beginning of treatment) any time throughout participation. Prior to beginning any study procedures, informed consent will be obtained orally and in writing. During the informed consent process, eligible participants will be provided with detailed information about the study, including their right to refuse or discontinue participation at any time and the fact that their decision to participate or decline will have no bearing on their standing within the criminal justice system.

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Eligibility Criteria:

Inclusion Criteria:

NIMH Branch:

Participants will be eligible to participate if they meet the following criteria: 18 years of age or older; IQ greater than or equal to 70; reading level of 4th grade or higher; no active symptoms of psychosis that would interfere with the individuals ability to participate in the group, no active suicidal ideation with intent or plan, able and willing to participate in group therapy; no scheduled release date before the end of the treatment group; and not currently enrolled in trauma focused treatment that is historical or involves processing of trauma itself. Other vulnerable populations within the prison setting (i.e., pregnant women or individuals appearing to lack the capacity to provide informed consent) will not be eligible for participation. Research suggests that a PCL-5 score between 31-33 indicates a probable diagnosis of PTSD. Accordingly, participants will be eligible to participate if they score a 31 or greater on the PCL-5 within two months of starting the study treatment. We will identify participants meeting these eligibility criteria from the pool of subjects who have previously participated in another IRB-approved protocol led by PI Dr. Michael Koenigs (2014-1106).

WPP Branch:

Taycheedah Correctional Institution:

Participants will be eligible to participate if they meet the following criteria: 18 years of age or older; no serious self-harm past 6-months (in clinical observation due to self-harm), no disciplinary segregation time in past 6-months, have not participated in the previous CPT groups with UW Project (NIMH branch), no active symptoms of psychosis that would interfere with the individual's ability to participate in the group, no active suicidal ideation with intent or plan, able and willing to participate in group therapy; not currently enrolled in trauma focused treatment that is historical or involves processing of trauma itself; no scheduled release date before the end of the treatment group; and able to understand the consent form as measured by the consent quiz. Research suggests that a PCL-5 score between 31-33 indicates a probable diagnosis of PTSD. Accordingly, participants will be eligible to participate if they score a 31 or greater on the PCL-5 within two months of starting the study treatment. We will identify participants meeting these eligibility criteria from the DOC list of residents on the waitlist for trauma treatment.

Kettle Moraine Correctional Institution:

Participants will be eligible to participate if they meet the following criteria: 18 years of age or older, no disciplinary placement (RHU) within the last 30 days; no active symptoms of psychosis that would interfere with the individual's ability to participate in the group, no active suicidal ideation with intent or plan, able and willing to participate in group therapy; not currently enrolled in trauma focused treatment that is historical or involves processing of trauma itself; no scheduled release date before the end of the treatment group; and able to understand the consent form as measured by the consent quiz. Research suggests that a PCL-5 score between 31-33 indicates a probable diagnosis of PTSD. Accordingly, participants will be eligible to participate if they score a 31 or greater on the PCL-5 within two months of starting the study treatment. We

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Exclusion Criteria:

NIMH Branch:

Participants will be eligible to participate if they meet the following criteria: 18 years of age or older; IQ greater than or equal to 70; reading level of 4th grade or higher; active symptoms of psychosis that would interfere with the individuals ability to participate in the group, active suicidal ideation with intent or plan, not able and willing to participate in group therapy; scheduled release date before the end of the treatment group; and currently enrolled in trauma focused treatment that is historical or involves processing of trauma itself. Other vulnerable populations within the prison setting (i.e., pregnant women or individuals appearing to lack the capacity to provide informed consent) will not be eligible for participation. Research suggests that a PCL-5 score between 31-33 indicates a probable diagnosis of PTSD. Accordingly, participants will be eligible to participate if they score a 31 or greater on the PCL-5 within two months of starting the study treatment.

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ALL WPP BRANCH:
Participants will also be told the specific limits to confidentiality. Participants will also be told the limits to confidentiality for research staff and DOC therapists, specifically. Research staff will have to report, if participants share an intention to harm themselves or others, disclose plans to escape or start a riot, or disclose any sexual activity between residents or residents and staff.

DOC therapists will follow the Limits of Confidentiality of Health Information outlined by the DOC, which are as follows:
Health care providers must report otherwise confidential information to the appropriate DOC authorities if it raises concern about a threat to you, a DAI or DJC correctional facility, community corrections operations, and/or public safety. This may include the following:
a. Overt/covert threats or harm to yourself or others.
b. Reports of any alleged sexual activity between an offender and any other person.
c. Reports of any sexual assault or intimidation between an offender and any other person.
d. Plans to riot or escape and possession of drugs or weapons.
e. Suspicious or unexplained deaths (homicides, suicides).
f. Unknown past criminal conduct that increases the potential risk to a correctional facility, community corrections operations, and/or the public, including self-reported acts of homicide, attempted homicide, and first or second-degree sexual assault.

Zoom Information:
While initial participant consent will be in-person, including signed, written consent, we will conduct verbal reconsent to address any minor changes to the consent form. This will include oral reconsent of participants associated with CP008, where participants will be provided with detailed information regarding the possibility of Zoom visits and changes in compensation and provide verbal reconsent to participate. Specifically, research staff will explain that some of the assessments may take place on Zoom for the remainder of their participation, and some assessments may take place in person. We will explain that the assessments will remain the same, and the only difference will be that they could take place over Zoom instead of in person. Then, participants will be given a chance to ask any questions about the changes and will be asked by study staff if they are comfortable doing virtual assessments. If they confirm that they are comfortable doing study visits over Zoom, we will continue with the assessment. We will track which assessments are conducted via Zoom and which are conducted in-person. If they are not comfortable doing study visits over Zoom, we will track this response and only conduct future study visits in person. NIMH branch participants have already consented to participate in Zoom visits for protocol 2014-1106. A waiver of signed reconsent is being requested for the reconsent plan under 45 CFR 46.117(c)(2) due to the fact that the changes in consent which we will communicate verbally and request verbal reconsent for present no more than minimal risk of harm to subjects and involve no procedures for which written consent is normally required outside of the research context.

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WPP Branch Only:
Participants will be reconsented using the updated consent form from the CP021 change, which informs them about the collection of RHU placements, conduct reports, clinical observations, reconviction, and re-incarceration through public records and/or requests from the Department of Corrections database. We will try to schedule two meetings for participants still housed at TCI to minimize the burden on facility staff. Facility staff will send a movement slip for them to meet with the UW project, and if they don't show up, we will call them down using the phone with a CO present. The re-consent process will only occur in person, as video calls would place an additional burden on facility staff and require more resources.

In the single branch version of this protocol prior to CP006, we enrolled 70 participants since that enrollment our protocol was revised, since then this is now a two-branch study. Our target enrollment thus includes the prior 70 participants from the prior protocol.

For the current two branch protocol, up to a total of 172 incarcerated individuals (76 male and 76 female) will participate in group assignment. To account for potential participant attrition between consent and group assignment (e.g., due to transfer, release, segregation) we will enroll a total of up to 270 participants (taking into account single-component version enrolled participants) based on eligibility from participation in protocol 2014-1106. Over the course of the study, we will run twelve rounds of CPT sessions; these rounds will include 12 CPT sessions occurring twice a week for a total of 6 weeks. Six of these rounds will be conducted at TCI, and Six will be conducted across OCI and FLCI. In addition, WPP branch of the study involves a waitlist control group; this group will receive the CPT treatment after the treatment group completes the treatment. Participation in the waitlist control group will not affect participation in any other treatments that are available at the facilities. . Sessions will be conducted at TCI and across OCI or FLCI.

Vulnerable Populations:
This study will enroll incarcerated individuals because rates of trauma exposure and PTSD are much higher in the prison population than the general population. Moreover, the focus of the current study is to examine the efficacy of providing empirically supported PTSD treatment in a correctional setting. Recruiting incarcerated individuals provides an opportunity to better understand if "best practice" mental health services in the community are feasible and efficacious in a prison setting. To further minimize risks for prisoners we will adhere to the requirements listed under section 45 CFR 46.303(d) of the Department of Health and Human Safety, minimal risk for incarcerated individuals. In addition, the following guidelines will be followed:

(1) The research under review represents one of the categories of research permissible under 45 CFR 46.306(a)(2). Protections: The research proposed within the present application falls within sections (i) and (iii) of this mandate. Regarding criterion (i), this study is designed to identify psychological and affective factors that may predispose a person to criminal behavior and incarceration in order to effectively design and implement treatment programs. Specifically,

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PTSD severity has been linked to increased risk of recidivism, and trauma is a hypothesized precursor to criminality [2,3,10].

(2) Any possible advantages accruing to the incarcerated individuals through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired. Protections: Incarcerated individuals will be paid $5.00/hr for their participation in the proposed work. This level of incentive would allow inmates to purchase items of modest value (e.g., snacks, hygiene products) from the prison canteen.

(3) The risks involved in the research are commensurate with risks that would be accepted by non-incarcerated volunteers. Protections: The psychological assessments and interventions undertaken entail only minimal risk for incarcerated individual and non-incarcerated populations, alike. We thus anticipate the creation of only minimal risk from these procedures, similar to those that would be encountered in non-incarcerated populations.

(4) Procedures for the selection of subjects within the prison are fair to all incarcerated individuals and immune from arbitrary intervention by prison authorities or incarcerated individuals. Protections: Subject exclusions are decided solely by the study team, and only according to the exclusion criteria designed for participant safety and experimental validity.

(5) The information is presented in language which is understandable to the subject population. Protections: All consent material will be provided in both written and oral format. All written consent material has been written so as to be readable to an individual with a 5th grade reading level. These consent materials have been used by Dr. Koenigs for the past nine years of prisoner research, and are well-received by prisoners with limited reading skills. For the NIMH branch, a reading test is provided to screen for low reading ability. Participants displaying reading skills below a grade 5 reading level, or with an IQ below 80, will be excluded from participation in the NIMH branch. For the WPP branch, we will utilize the Consent Quiz as a measure of intellectual ability and reading level. Thus, we can be sure that all participating incarcerated individuals will show sufficient reading skills to make informed decisions throughout the study procedures. Items on some questionnaire measures may include certain words above this reading level. Incarcerated individuals will be encouraged to ask the trained research assistants for definitions of any words that they do not understand.

(6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each incarcerated individual is clearly informed in advance that participation in the research will have no effect on his parole. Protections: Incarcerated individuals will be informed, both orally and in writing, during the initial consenting procedure, that their decision about whether or not to participate in this study will have no bearing on their status within the correctional system, and that any information collected within this study will not be included in their prison records. Incarcerated

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individuals will be informed that the researchers have no direct affiliation with the Wisconsin DOC. Finally, incarcerated individuals will be informed that all of the identifiable data collected within the study will be stored within a locked cabinet or on a secure password-protected server within our laboratory, and nowhere else. Prison officials will have no access to the data collected in the study, and no information will be used to influence prisoner's treatment in prison. From the time of inclusion within the study, only unique numerical identifiers will be used on all study material. All identifying information will be stored in locked filing cabinets or on secure servers in locked offices within the PI's laboratory.

(7) Where the IRB finds that there may be need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual incarcerated individuals' sentences, and for informing participants of this fact. At least one member of the IRB must be an incarcerated individual, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB, only one IRB need satisfy this requirement. Protections: As has been standard at the University of Wisconsin-Madison, the IRB will include at least one prisoner representative when evaluating this research protocol. We do not anticipate need for follow-up examinations, as there should be no long-term health risks of any of the procedures performed within the study. Incarcerated individuals will, however, be provided with the PI's work phone number and mailing address, and will be encouraged to contacting the PI if they have any questions or concerns, or experience any effects of study participation.

WPP Branch

This study might enroll individuals with intellectual disabilities (e.g., low reading level) because we are basing our eligibility criteria off the DOC's eligibility requirements for participation in treatment. The DOC does not limit eligibility based on intellectual ability. Participation in this study presents minimal risk to individuals with intellectual disabilities. With respect to the possibility of including participants with significant intellectual disabilities and/or low reading level, we will utilize the consent quiz to assess for ability to provide informed consent. The consent quiz is based on the U-ARE protocol for decisional capacity assessment for clinical research[53], and is more extensive in the questions asked.

This study might enroll pregnant persons because we are basing our eligibility criteria off the DOC's eligibility requirements for participation in treatment. The DOC does not limit eligibility based on pregnancy status. Participation in this study presents minimal risk to individuals who may be pregnant. In order to further limit any risk, we will not be collecting information about pregnancy; therefore, pregnancy status will not be identified or recorded.

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NIMH Branch:

In this branch, we will run CPT sessions that will take place over 6 to 12 weeks depending on session frequency within the female prison (TCI) and across male prisons (OCI and FLCI) within two years. A total of 72 incarcerated individuals (36 male and 36 female) will participate.

WPP Branch:

In this branch, we will run CPT sessions that will take place over 6 or 12-week, and obtain data from a waitlist control group within the female prison (TCI) and across male prisons (FLCI or OCI) within three years. A total of 80 participants (40 male and 60 female) will participate in group randomization

Research Design and Procedures:

Potential participants will be contacted by either calling them over the phone system within the prison or scheduling a time to meet with them about the study through individual prison scheduling systems. When they arrive to the private testing room, they are asked if they would like to learn about the study and potentially participate. If so, we begin the consent process. Eligible participants will complete the PCL-5 to ascertain current PTSD symptomology and probable diagnosis. Study consent and initial assessments will be conducted by trained graduate students, study staff, and/or advanced undergraduates with extensive experience working on our prison project. Midpoint, post-treatment, and follow-up interview sessions may take place over Zoom or in person. All focus groups will be conducted in person. If at any point a participant withdraws from the study, they will no longer be contacted for participation.

NIMH Branch:

Participants will be assigned to a CPT group if they meet PCL-5 criteria for a current probable PTSD diagnosis. CPT groups will engage in 12, 90-minute treatment sessions (18 hours total). With the optional opportunity to take 15-20 minutes after each session to de-stress and calm down if necessary. These sessions will take place over 6 to 12 weeks, depending on session frequency. The CPT group-members are also asked to complete weekly homework (approximately 12 hours total) as well as a post-intervention focus group and will have one follow up CPT session 6-8 weeks post-treatment. A maximum of 8 participants, but no less than 3 will be included in each CPT group. Participants will be able to continue any ongoing treatment/interventions they are engaged in within the institution as long as it meets our eligibility requirements.

In addition to the treatment groups, CPT group members will also complete a number of additional testing sessions throughout the course of treatment. They will participate in a pre-treatment testing session two weeks prior to the start of treatment. They will be asked to complete the PCL-5 at the beginning of each treatment session. After treatment session 5, group members will complete mid-treatment testing assessments. Participants will be called down individually to complete these assessments in a private room with a research assistant after completing the 5th therapy session,

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but before completing the 8th therapy session. Group members will then complete post-treatment testing within one week after completing treatment (group session 12). One month after the treatment is completed, group members will complete the first round of follow-up testing. Three months after the treatment is completed, group members will complete the final round of follow-up testing. Post-one-month, and three-month follow up-testing will follow the same procedure as pre- and mid-testing. In total, group members will be asked to complete 18 sessions in total (pre-, mid-, post-, one-month follow up-testing, three-month follow-up testing, 12 treatment groups, and 1 post-intervention focus group).

WPP Branch:

Participants will be randomly assigned to the CPT or the active control group~~s~~ (randomization process specified in "Randomization and Blinding"). The CPT group will engage in 12, 90-minute treatment sessions (18 hours total). With the optional opportunity to take 15-20 minutes after each session to de-stress and calm down if necessary. These sessions will take place over 6 to 12 weeks, depending on session frequency. CPT group-members are also asked to complete weekly homework (approximately 12 hours total). A maximum of 8 participants, but no less than 3 will be included in each CPT group. When the waitlist control group reaches the treatment phase, if the participant count fall below 3, additional participants will be enrolled to maintain sufficient numbers. Data collection during treatment will mirror that of the active waitlist control group. Participants will be notified via institutional mail which group they have been enrolled in.

In addition to the treatment groups, CPT and control group members will complete a PCL-5 at the beginning of each session. As well as, pre-treatment testing session two weeks prior to the start of treatment. After treatment session 5, CPT and control group members will complete mid-treatment testing assessments. Participants will be called down individually to complete these assessments in a private room with a research assistant after completing the 5th therapy session, but before completing the 8th therapy session. CPT and control group members will then complete post-treatment testing within one week after completing week 6 of treatment. One month after the treatment is completed, CPT and control group members will complete follow-up testing and interviewing about their experience in the treatment groups and will have one follow up CPT session 6-8 weeks post-treatment. Post-treatment and one-month follow up- testing will follow the same procedure as pre-treatment and mid-treatment testing. Final follow-up will occur three months after the end of treatment. Procedures will be the same as other timepoint follow-ups. CPT and control group members will be asked to complete 18 sessions in total (pre-treatment, mid-treatment, post- treatment, one-month follow up-testing, three-month follow-up treatment, 12 group sessions and one follow-up CPT session).

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Measures and Assessments:
NIMH Branch: If participants have completed any of the following measures or assessments as part of study 2014-1106 two months or less from the time of enrollment for this study, we will not complete them again. Instead, we will obtain this data from the PI's database (2014-0350).

WPP Branch: We will not use previously-collected data from any participants who may have completed these assessments through study 2014-1106, given the confidentiality rules outlined in that study. Participants who consent to the WPP branch will be re-administered each assessment.

Baseline Assessments:

These measures will be collected prior to the study and group assignment (across multiple visits) and used to examine potential moderating variables (see "Measurement of Specific Aims").

PTSD: We will determine PTSD diagnosis through the PCL-5. The PCL-5 is a 20-item self-report measure that assesses for DSM-5 symptoms of PTSD [52].
NIMH Branch: If PTSD status has been assessed through protocol 2014-1106 more than two months prior to baseline assessments, we will update this information during baseline assessments as needed. To update symptoms, study staff will meet with the participant to re-evaluate current symptoms of PTSD

Trauma History: We will administer the Trauma History Questionnaire (THQ)† in conjunction with the CAPS-5. The Trauma History Questionnaire (THQ) is 24-item scale assessing experiences of traumatic events [21]. We will also administer two self-report questionnaires that assess distinct (but overlapping) aspects of lifetime trauma and stress exposure: The Life Events Checklist-5† (LEC-5; a 17-item self-report measure of potentially traumatic (i.e., life-threatening or severely harmful) events during the participant's lifetime. [22] The LEC-5 will be administered the first time the PCL-5 is completed. The Childhood Trauma Questionnaire† (CTQ; 29-item scale assessing severity of physical abuse, physical neglect, emotional abuse, emotional neglect, and sexual abuse under age 18) [23].

Treatment history: Participants will self-report previous experiences with treatment for any psychiatric illness or psychological problems (type of treatment, dates, and perceived benefit).

Demographics: We will collect sex, age, race, and years of education through self-report. Family socioeconomic status will be assessed with the Hollingshead questionnaire† [24].

Cognitive function: We will use scores on the Wechsler Abbreviated Scale of Intelligence-Second Edition to measure intelligence, verbal comprehension, working memory, and processing speed from protocol 2014-1106 [25].

Substance use history: We will assess substance use history with the Addiction Severity Index (ASI)† [27].

† For the NIMH branch, any historical data (i.e., information that is stable and is not expected to change over time) that has already been collected through protocol 2014-1106, we will obtain this data from the PI's database (2014-0350) and will not re-administer these assessments under the current protocol.

Medication use: We will collect medication name, dose, and duration of use (past month) through self-report. If medication use has already been assessed through protocol 2014-1106, we will update this information during baseline assessments.

Additional Measures:

Client Satisfaction: We will assess participant satisfaction with therapeutic interventions using the Client Satisfaction Questionnaire-8 (CSQ-8) [28]. Participants will complete this at the one-week post-treatment timepoint.

Psychopathy: We will assess psychopathic personality traits-with the Psychopathic Personality Inventory (PPI-SF) [29].

Time served: We will collect time served through participant self-report.

Isolation Time: We will collect data on time spent in Segregated Housing through participant self-report.

# of Requests for Services: We will collect data on the number of requests each participant requests for psychological services within one year before and after the treatment, as well as any requests for psychological services since the beginning of treatment. This information will be collected from the DOC central office after the completion of treatment.

# of Actual Service Contacts: We will collect data on the number of contacts each participant has with the Psychological Services Unit within the one year before and after the treatment, as well as any contacts with the Psychological Services Unit since the beginning of treatment. This information will be collected from the DOC central office after the completion of treatment.

# of Clinical Observation Placements (Optional measure for participants): We will collect data on the number of clinical observation placements each participant has with the Psychological Services Unit within the one year before and after the treatment, as well as any contacts with the Psychological Services Unit since the beginning of treatment. This information will be collected from the DOC central office after the completion of treatment.

Restricted Housing Placements (Optional measure for participant)s: We will collect data on the number of restricted housing placements and how long each restricted housing placement was for each participant within the one year before and after the treatment. This information will be collected from the DOC central office after the completion of treatment.

Conduct Reports(Optional measure for participants): We will collect data on the conduct reports received for each participant within the one year before and after treatment. This information will be collected from the DOC central office after the completion of treatment.

Recidivism: Recidivism rates will be provided by the Research and Policy Unit of the Wisconsin DOC. This information includes the date of release, 1-, 2-, and 3-year recidivism status (i.e., whether someone recidivated during the first, second, or third year after release), and the date of

recidivism (if applicable).

Other Current Treatment: Participants will be asked what treatment groups they are currently enrolled in during the initial screening. Participants will self-report current and previous experiences with treatment for any psychiatric illness or psychological problems (type of treatment, dates, and perceived benefit) during baseline, midpoint, and post assessments.

Drop-Out: If participants decide to discontinue treatment, study staff will ask participants to indicate their reasons for doing so as a measure of treatment acceptability.

Treatment Expectancy: Expectations for treatment will be assessed after session 2 of group treatment using the CEQ (Credibility/Expectancy Questionnaire)[30].

Therapeutic Alliance: Alliance will be measured using the Working Alliance Inventory-Short Revised (WAI-SR)[31] and the California Psychotherapy Alliance Scale for Group Psychotherapy (CALPAS-P)[32]. Participants will complete these at the one-week post-treatment timepoint.

Questionnaires:

All participants will complete the same battery of questionnaires and tasks at pre-, mid-, post-, one-month and three-month follow-up timepoints. This battery will include: PTSD Checklist for DSM-5 (PCL-5) [33], Beck Depression Inventory-II (BDI-II) [34], Beck Anxiety Inventory (BAI) [35], Beck Hopelessness Scale [36], the Posttraumatic Cognitions Inventory [37], Buss-Perry Aggression Questionnaire (BPAQ) [38], Impulsive Behavior Scale (UPPS-P) [39], and Difficulties in Emotion Regulation Scale (DERS) [40], Patient Health Questionnaire (PHQ-9)[60].

The BDI-II will be reviewed by a study team member immediately after the participant completes it. If any participant indicates a desire to harm themselves or commit suicide, the research assistants will contact the prison medical staff. This is one of the only instances when the researcher would breach confidentiality (participant is risk to harm self, other, reveals plans to escape or start a riot). If participant expressed suicidal ideation during any assessments, we will follow up by using the Columbia-Suicide Severity Rating Scale Screen Version – Recent (C-SSRS-SV) [41], a scale to rate the subject's risk. We will only ask about ideation within the last month (current). We will ask about suicidal ideation and intensity and any suicidal behavior. Participants will be considered at suicide risk if they endorse ≥2 on question #9 (suicidal ideation question) of the BDI-II or if they endorse any current plan to harm themselves. If a participant endorses a plan to hurt themselves, the C-SSRS-SV will be administered to determine suicide risk. If there are any imminent safety concerns (i.e., endorses current suicidal ideation/behaviors), research staff will notify the institution's psychologist, and the participant will be escorted by prison staff to the mental health services office.

Participants will also complete the Patient Health Questionnaire (PHQ-9) [60] weeklt, as a check-in to monitor depressive symptoms and address suicidal and self-harm risk. The PHQ-9 will be reviewed by a study team member after each participant completes it at each timepoint. If participants endorse a 1 ("Several days"), 2 ("More than half the days") , or 3 ("Nearly every day")

on item 9 of the PHQ-9, study staff will immediately follow-up by administering the C-SSRS-SV and adhere to the same follow-up protocol outlined above.

Qualitative Data Collection:

NIMH Branch:
Focus Groups: Focus groups will be aimed at collecting qualitative data examining acceptability of group CPT. Focus groups meet 1 time and will occur the week following treatment completion. Focus group members will be comprised of the same participants that completed the treatment protocol. Focus groups will be conducted by a trained graduate student or study staff member that did not lead the CPT treatment groups. Focus groups will last approximately 2 hours and will consist of open-ended questions aimed at understanding what participants liked and didn't like about the treatment, such as content, engagement, and format of the sessions. Questions will be limited to assessments of the intervention and ways it can be improved regarding issues of acceptability; no personal or sensitive information will be collected.

WPP Branch:
Individual Interviews: Individual interviews will be aimed at issues related to efficacy of treatment groups. Participants will complete one individual interview focused on efficacy of their assigned treatment at the 1-month follow-up timepoint. This interview will be conducted by trained graduate student or study staff members that did not lead either treatment group. Individual interviews will last approximately 1 hour. Interviews will consist of open-ended questions aimed at understanding the potential effects of the assigned treatments and will address topics such as outcomes following treatment and specific skills and concepts. Questions will be limited to assessments of the intervention and ways it can be improved regarding issues of acceptability.

Randomization and Blinding:

NIMH Branch:
Randomization and blinding procedures are not applicable to the NIMH Branch, as there is only one condition to which participants will be assigned to.

WPP Branch**:**
To ensure that our randomization process results in treatment groups that are balanced on key variables that might affect treatment response, participants will be assigned to groups through stratified randomization, in which randomization occurs within specific strata of different potential moderating variables and assures equal assignment to each group across these variables. Participants will be stratified/randomized based on PTSD severity (PCL-5 total score).. The stratified randomization will use group code numbers (1 & 2) rather than the intervention title, thus eliminating any chance of systematically biasing the group assignment.

While it is impossible for the therapists and participants to be blind to the group assignment, the research members performing the pre-treatment, mid-treatment, post-treatment, one-month and three-month follow-up assessments will be blind to the group assignment. The study therapist will not conduct assessments once participants have assigned to their respective treatments (e.g., pre-, mid-, post-, or follow-up assessments). Additionally, one graduate research assistant will schedule

participants according to the randomization, thus minimizing the possibility of systematically biasing the outcome and mediator assessments.

Treatment:

NIMH & WPP Branches:

Each CPT group will enroll 6-8 members and will meet weekly or biweekly for 12 group sessions including one follow up CPT session. Participants will be referred to by their preferred first names. The CPT protocol will follow the published manual [15]. Session 1 begins with orientation to group treatment and group rules, education about PTSD, an overview of treatment, and an assignment to write an impact statement about the personal meaning and effect of the traumatic event. After reading and discussing the meaning of the traumatic event in Session 2, group members are introduced to the identification of and relationship among events, thoughts, and emotions. At the end of Session 3, group members are given the assignment of recording events, thoughts, and emotions throughout the week to establish the relationships between thoughts and emotions within their own lives. During Session 4, cognitive therapy begins with Socratic questions regarding self-blame and other distortions regarding the event. In Sessions 5-6, the focus of the therapy shifts to teaching clients to challenge and change their beliefs about the meaning of the event and the implications of the trauma for their lives. Group members are first taught to challenge a single thought by asking themselves a series of questions. They are then taught to identify problematic patterns of cognitions that have come to represent a style of responding. From that point, beginning with Session 7, group members use worksheets that incorporate the earlier activities as well as the development of alternative, more balanced self-statements. In Sessions 7-12, group members are asked to focus on one of the five core themes of CPT each week (safety, trust, power/control, esteem, or intimacy) and correct any overgeneralized beliefs related to that theme. In Session 11, group members are asked to rewrite their impact statements to reflect their current beliefs, and these revised statements are then used in Session 12 to evaluate gains made in treatment and areas in which they wish to continue working. Following the completion of the 12 CPT sessions, an additional follow-up group CPT therapy session will be provided. This follow-up CPT session is recommended by the CPT manual and typically occurs 2-3 months after the end of the 12-session treatment group. The group follow-up CPT session is designed to check-in with participants to see how they are doing, work through any problems/difficulties they have had, and to reinforce the strategies and skills they learned from the treatment group. At the start of each treatment session, the participants will be asked to complete the PCL-5. At the end of treatment sessions, participants will be given the option to de-stress for 15-20 minutes.

Treatment notes will be completed after each group session to document the content covered in the session and to track the attendance and homework completion of group members. Group members will not receive individual psychotherapy notes, and no information from this study will be added to participants' medical record.

WPP Branch:

The active control course will follow the structure from extant studies using waitlist control groups [42]. This group will mirror the CPT group in all aspects of frequency and duration (over 6 to 12 weeks depending on session frequency, 90-minute sessions) as well as group size (approximately

6-8 participants). Treatment notes will be completed after each group session to document the content covered in the session and to track the attendance of group members. Group members will not receive individual psychotherapy notes, and no information from this study will be added to participants' medical record.

Therapists:

Therapists will receive training prior to administering treatment at a level that will emulate the personnel and training resources that will realistically be available in the correctional setting (i.e., to make the results of this research program generalizable and scalable to correctional institutions). Consultation and clinical supervision/oversight will be provided by licensed clinical psychologists with experience in training, student supervision, and clinical research and with particular expertise in CPT (Co-I Dr. Monson; Dr. Maine). We believe this level of therapist training will be sufficient for this project, as a previous study showed group CPT to be effective for reducing PTSD symptoms in a resource-poor country where the therapists had minimal secondary education and the patients had extremely limited literacy [43].

NIMH Branch:
The therapists for the CPT groups will be a graduate student with masters-level training in clinical psychology or a community provider with CPT training. The community provider will also have master-level training in clinical psychology or certification as a peer specialist.

WPP Branch:
The therapists for the CPT groups will be psychological services staff at each facility with CPT training.

Measurement of Specific Aims

NIMH Branch:
Specific Aim #1: Our assessment of feasibility of the interventions will be determined by measures of eligibility, participation, retention (primary measure), compliance with intervention activities, adherence to intervention elements, competence of intervention elements, and safety.

Primary Outcome Measure:
Retention will be measured as the percentage of residents attending all 12 sessions. Retention rates for CPT in non-incarcerated samples are typically 80% or less [15]; hence, our study goal is ≥80% retention. Retention is our primary measure of feasibility for this aim.

Secondary Outcome Measures:
Eligibility will be measured as the percentage of participants who meet the full set of inclusion criteria. We will also compute the percentages of participants who are excluded for each individual criterion separately, so we are able to discern the relative impact of each criterion on study eligibility.

Participation will be measured as the percentage of eligible participants agreeing to

participate. Our study goal is ≥75% participation of eligible participants.

Compliance will be measured as the percentage of retained participants performing intervention activities during session (e.g., attending to and contributing to the discussion); the percentage of participants completing the homework assignment each week; and the percentage of participants fully completing the pre-, mid-, and post-intervention assessment batteries. Our study goal is ≥80% compliance of participants retained in the study.

Adherence by the therapists will be measured by ratings of the presence or absence of five session elements (scores 0-5) by the clinical supervisors, as in previous CPT studies [16, 18]. Adherence ratings will be collected for two audiotaped group sessions out of each 12-session intervention (16.7% of sessions). Our study goal is adherence scores ≥4 for each session.

Competence of the therapists will be measured by ratings of the quality of session elements (scores 1-7; 1="not satisfactory", 4="satisfactory", 7="excellent") by the clinical supervisors, as in previous CPT studies [16,18]. Competence ratings will be collected for two audiotaped group sessions out of each 12-session intervention (16.7% of sessions). Our study goal is competence scores ≥4 for each session.

Safety will be measured through the suicidal ideation item on Beck Depression Inventory-II [34], administered at the pre-, mid-, and post-intervention assessments. Participants who endorse current suicidal ideation will be referred to mental health services within the institution.

In sum, we will consider the study successful in terms of feasibility if we meet the following thresholds for each intervention: participation rate ≥75% of eligible participants; retention rate ≥80% of participating participants; compliance rate ≥80% among retained participants; adherence scores ≥4; competence scores ≥4; and ≤10% of participating participants reporting an increase in suicidal ideation.

Specific Aim #2: Our assessment of acceptability of the interventions will be determined through measures of client satisfaction and reasons for treatment dropout.

Primary Outcome Measure: Acceptability will be measured by client satisfaction using participant scores on the CSQ-8. Other studies of CPT [44] have established acceptability of interventions using the CTQ-8 when mean scores are ≥ 27; hence, our study goal is scores of ≥ 27 on the CTQ-8. Client satisfaction is our primary measure of feasibility for this aim.

Secondary Outcome Measures: Reasons for discontinuation of treatment will be measured through participant self-report.

We will consider the study successful in terms of acceptability if client satisfaction mean ratings

are ≥ 27 on the CTQ-8.

Specific Aim #3: Our assessment of feasibility of assessment distribution will be determined through measures of assessment completion.

Primary Outcome Measure:
Assessment completion will be measured as the percentage of PCL-5 at each timepoint for the number of participants retained at that timepoint.

We will consider the study successful in terms of assessment distribution feasibility if 100% of PCL-5 assessments at each timepoint are completed for each participant retained at that timepoint.

WPP Branch:
Specific Aim #1: To assess preliminary efficacy, we will collect primary and secondary outcome data at the pre-, mid-, and all post-intervention time points.

Primary Outcome Measure:
PTSD symptom severity will be measured with the PTSD Checklist for DSM-5 (PCL-5) [33].

Secondary Outcome Measures:
Depression symptom severity will be measured with the BDI-II [34]. Anxiety symptom severity will be measured with the BAI [35].

Analysis of effectiveness: Treatment efficacy will be determined by the change (from pre-intervention to post-intervention timepoints) for the primary outcome (PTSD) and secondary outcomes (e.g., depression) for each group. Repeated measures ANOVAs will be conducted for each group. One-way ANOVA will be used to test for group differences in score changes from pre-intervention to post-intervention, with follow-up pairwise tests (if warranted), using Tukey's post-hoc tests. IQ and age will be included as covariates in all analyses.

Exploratory analysis of moderators: As an exploratory follow-up analysis, we will examine potential moderators of effectiveness (details of measures in "Baseline Assessments" above). Following published guidelines for randomized controlled trials [45,46], moderators of treatment outcome will be tested in regression models, in which the post-intervention primary outcome measure (PCL-5 score) is regressed simultaneously onto 1) dummy-coded group assignment (CPT vs control), 2) the hypothesized moderator, 3) the group x hypothesized moderator interaction, 4) the pre-intervention primary outcome measure (PCL-5 score), and 5) any covariates of non-interest. The regression coefficients of interest are the main effect of the moderator and its interaction with group. A main effect independent of an interaction indicates the moderator predicts symptom reduction regardless of group assignment. An interaction with group indicates that the moderator predicts symptom reduction more strongly in one of the treatment conditions (i.e., specificity of moderation).

Adherence by the therapists will be measured by ratings of the presence or absence of five session elements (scores 0-5) by the clinical supervisors, as in previous CPT studies [16,18]. Adherence ratings will be collected for two audiotaped group sessions out of each 12-session intervention (16.7% of sessions). Our study goal is adherence scores ≥4 for each session.

Competence of the therapists will be measured by ratings of the quality of session elements (scores 1-7; 1="not satisfactory", 4="satisfactory", 7="excellent") by the clinical supervisors, as in previous CPT studies [16,18]. Competence ratings will be collected for two audiotaped group sessions out of each 12-session intervention (16.7% of sessions). Our study goal is competence scores ≥4 for each session.

Specific Aim #2: To measure previously established mediators of CPT efficacy (hopelessness, self-blame, and negative self-related thoughts), as in previous studies with non-incarcerated populations [47–49], we will administer the Beck Hopelessness Scale [36] and the Posttraumatic Cognitions Inventory [37].

Statistical test of mediation: Mediation analyses will be conducted according to published guidelines for randomized controlled trials [45,46] in order to determine the extent to which changes in the proposed mediators of treatment effectiveness (described above) account for decreases in PTSD symptom severity (PCL-5 score) over the course of treatment. These mediation analyses will be conducted with regression models, in which the hypothesized mediator is regressed onto group assignment controlling for pre-intervention mediator measures (i.e., path a), and the post-intervention PCL-5 score is regressed onto the post-intervention mediator measure, controlling for pre-intervention measures and group assignment (i.e., path b). The indirect mediation effects (i.e., product of a and b paths) will be calculated using bootstrapped confidence intervals [49]. Statistical significance of the indirect effect will be concluded if the confidence interval of the indirect effect does not include zero.

Current Alternatives to Research Participation:

Participation in this study will have no effect on the availability of other treatments for potential participants. Participants may have the opportunity (or be required) to engage in other corrections-based treatment groups based on their criminal history (e.g., substance abuse treatment, domestic violence treatment, sex offender treatment, anger management), however there is no evidence that these treatment protocols influence PTSD symptomology. Outside of group therapy, incarcerated individuals may have the opportunity to meet individually with a licensed psychologist or psychiatrist semi-regularly (e.g., monthly) depending on their diagnosis and level-of-need.

Participant Recruitment:

NIMH: Potential eligible participants will be identified through a research database maintained by the P.I. (2014-0350). This database includes demographic (e.g. age, race, IQ) and psychological variables (e.g., psychopathy score, substance abuse) collected during our initial screening and interviewing protocol. Participants who previously scored highly on a self-report measure of PTSD symptomology (PTSD Checklist for DSM-5 > 33[33]) that is included in our initial screening process will be prioritized for this study. All prison studies that we conduct utilize this database to recruit eligible participants.

WPP: Potential eligible participants will be identified through the trauma treatment waitlist at the facilities. These participants have been screened for active psychosis, suicidality, and self-harm or will be identified through a research database maintained by the P.I. (2014-0350). This database includes demographic (e.g. age, race, IQ) and psychological variables (e.g., psychopathy score, substance abuse) collected during our initial screening and interviewing protocol. Participants who previously scored highly on a self-report measure of PTSD symptomology (PTSD Checklist for DSM-5 > 33[33]) that is included in our initial screening process will be prioritized for this study. All prison studies that we conduct utilize this database to recruit eligible participants.

Study Stopping:
Participants can withdraw themselves from this study at any time. Participants may be withdrawn from the study treatment group under the following circumstances; if they endorse suicidal ideations with intent or plan and/or it significantly increases throughout the course of treatment (explained below under "Suicidality Risk"), PTSD symptoms significantly worsen over time due to treatment per participants report and clinicians' discretion (explained below under "PTSD Symptoms Worsening"), noncompliance with treatment requirements or consistently being harmful or disruptive to other group members or the therapist, or serious adverse events directly related to treatment. In the event that one of these circumstances occurs and the participant is not withdrawn from the study based on clinician discretion, the clinician will document this circumstance and rationale. A serious adverse event is classified as life threatening, requires inpatient hospitalization, persistent or significant disability or incapacity, or is an important medical event [51].

Circumstances that warrant consideration for termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to subjects
- PTSD Symptoms Worsening
    - An increase of 10 points or more on the PCL is considered to be clinically significant, although there is currently no widely accepted clinically significant change on the PCL-5 (which is used to assess PTSD symptoms in this study) [55]. Preliminary research suggests a change in score of 15-18 or greater on the PCL-5 is a reliable change [59]. Considering that research regarding what constitutes a reliable change on the PCL-5 is still ongoing, our study will use a more conservative value of a 10-point increase on the PCL-5 to trigger a meeting between the clinician and participant. As such, if a participant has a 10-point or greater increase on the PCL-5 relative to their baseline PCL-5 score, the study clinician will check-in with the participant regarding their symptoms and safety. If this 10-point or greater increase in PCL-5 score relative to baseline is maintained over three weeks, the study clinician will check-in again with the participant, and consider withdrawing them after 3 weeks of increased symptoms. The study clinician will also meet each week with the participant if they have a sustained 10-point or greater increase in score relative to baseline as a weekly check-in. In considering participant withdrawal, the clinician will make a clinical judgment based on the participant's scores and their expertise as to whether the participant ought

to be withdrawn for their safety. This procedure for discontinuing participation based on the therapist's clinical judgment pursuant to worsening of PTSD symptoms is consistent with recent clinical trials of CPT conducted by leading experts in the field (e.g., Schurr et al., 2022; Sloan et al., 2022)

- Suicidality Risk
    - If a participant scores a 2 or 3 on item 9 of the BDI-II or score a 1, 2, or 3 on item 9 of the PHQ-9, the research staff with administer the C-SSRS-SV. If any participant indicates "active suicidal ideation with some intent to act" (item 4) or "active suicidal ideation with specific plan and intent" (item 5) on the C-SSRS-SV, the participant will be withdrawn from the treatment group and staff will adhere to the adverse events follow-up protocol outlined in the AE sections.

If a participant is withdrawn by the clinician, they will be offered the option to complete study-related follow-ups. If the participant chooses not to complete the follow-up activities, they may withdraw from the study entirely.

WPP Branch Study Stopping Rules:

1. Participants who miss more than three sessions will not be allowed to rejoin the treatment group. Participants will be notified through internal mail or in person following their return to group.
2. Participants will be removed from group if they exhibit self-harming behaviors requiring clinical observation.
3. Lack of engagement as assessed by continually not paying attention during group, not completing homework, not taking notes during group, and not engaging in discussion.

Risk/Benefit Assessment

Known Potential Benefits to the Subjects:

Participants may experience an improvement in how they are feeling after completing a therapy group. However, we cannot promise this will happen. Participation in this research study may benefit other people in the future by helping us learn more about how to treat PTSD in currently incarcerated individuals.

Known Potential Risks:

Some subjects may find the questionnaires to be boring or tiring. They may also feel uncomfortable with sharing information about their emotions and personality.

While completing the therapy groups, some people may feel upset or emotional talking about their feelings and experiences with others. Participants may also experience temporary increases in mental health symptoms, like depression, anxiety, sleep disturbances, and other PTSD symptoms [56-58;54] Peterson et al. (2022) report that the most common adverse events in their CPT treatment for active-duty military and veteran participants with PTSD were mental health symptoms, including, nightmares (7.5%), sleep difficulty (5.8%), depression (5.0%), anxiety (4.2%), and irritability (4.2%). Similarly, Sloan et al. (2022) report that the most common adverse events in their CPT treatment for active service military members with PTSD were mental health symptoms such as anxiety, depression, and sleep disturbances. In rare cases, such symptoms can

be severe. In a large-scale study of CPT for veterans with military-related PTSD, researchers reported the most significant "attributed" or "possibly attributed" adverse event for any of the study treatment (psychiatric hospitalization), was "attributed" in only 1 out of 461 CPT participants (0.002%) and "possibly attributed" in 6 out of 461 CPT participants (0.01%) [51]. This indicates that severe adverse events, such as psychiatric hospitalization, are rare in the context of this study and unlikely to be attributable to CPT treatment.

One other risk of taking part in this study is that the participant's study information could become known to someone who is not involved in the study. For instance, someone might find out that the participant has a history of trauma. Breaking confidentiality in this way could happen if any of the data we collected were to be lost or stolen from the laboratory or if any data stored in the electronic database were damaged.

Multiple Sites:

All data for this study will be collected at OCI, FLCI, or TCI. Dr. Koenigs and his staff have an extensive and ongoing program of psychological research with residents at all three sites. Neither the prisons nor the Wisconsin Department of Corrections (DOC) has a legally constituted IRB. However, the DOC has a formal Research Review Committee. Before conducting research with the DOC, it is necessary for investigators to receive both approval by a legally constituted IRB and the DOC Research Review Committee.

Research activities conducted at non-UW sites (OCI, FLCI, TCI) will be monitored by experienced research staff (graduate students, Research Specialists, P.I.) to ensure that the activities are within the guidelines of the protocol. Research team members will be trained to conduct the research activities according to IRB guidelines and will immediately report any complications to the research staff and the P.I. The P.I. will meet weekly with the entire study team to ensure regular communication regarding the study procedures. Any unanticipated problems, adverse events, or protocol deviations will be monitored by the study therapists and will then be reported to Dr. Koenigs. Examples of potential reportable events include participant drop out due to unexpectedly high emotional distress from participating in the group or a participant report of significant increase in suicidal ideation. Dr. Koenigs will relay these events to the UW-Madison HS-IRB. If any protocol changes are necessary in response to an unanticipated problem, Dr. Koenigs will communicate this to the UW-personnel working on the study, and the study therapists will monitor such changes on-site to ensure they are followed.

Because the multiple study sites are not involved in the research study (the studies are simply conducted at these sites), communication between research staff and the study sites is limited to logistics of scheduling (e.g., reserving rooms in the prison). Specific study information (e.g., protocol updates) will not be disseminated to the study sites.

The UW-Madison HS-IRB is the only IRB that will be approving documents and consent forms for this study. Therefore, there is no need to review IRB approved documents from other sites.

Monitoring and Reporting Adverse Events:

A serious adverse event can be classified as life threatening, requires inpatient hospitalization, persistent or significant disability or incapacity, or is an important medical event[51].

Participants will be monitored by a study therapist or study team member during all study visits. Study visits include baselines, follow up interviews, treatment groups, and focus groups. At the start of every session, the study team or therapist will hand out an independent sheet for each participant with the following questions,

1. "Have you had any significant/negative psychological, social, physical, or other negative life events in the last week? "
2. How did this event make you feel?
3. When did this situation happen?
4. Is the situation ongoing? If not what day/date did it end?
5. What this situation related to this treatment?

Once finished, the therapist will collect the document and check the response. The response to this question will be tracked and monitored each session. If the adverse events needs follow up, the therapist or study team member will have a conversation with the participant.

The study therapist and study team members will be required to notice any clinically significant changes in PTSD symptoms or any worsening symptoms and determine adverse events. The study team or study therapists will perform structured assessments (i.e., PCL-5, PHQ-9) each the beginning of each group. We will add a 15-minute period at the beginning of each group session specifically for check-ins and administration of the PCL-5 and PHQ-9. Scores from the PCL-5 and PHQ-9 will be reviewed during this period, and will be added to a tracking document that has separate columns for each measure at each timepoint assessment (i.e., baseline, group sessions, midpoint, post-treatment). The tracking document will also include columns to indicate whether the PCL-5 score has increased by 10 or more points and whether the participant reported a 1, 2, or 3 on item 9 of the PHQ-9. Additionally, a research staff member will stay in the treatment room to assist the study therapist with administration, review, tracking of the participant scores, and assessment of SI via the C-SSRS-SV as needed.

The study team will conduct the BDI-II at each timepoint assessment (baseline, mid-, post-, 1 month, 3 month follow up) . We will also use a tracking procedure to document BDI-II scores including whether the participant reported a 2 or 3 on item 9. Additionally, a research staff member will administer, review, and track the participant score, and assessment of SI via the C-SSRS-SV as needed.

Each change in the PCL-5 or the PHQ-9/BDI-II that meets the definition of an AE will be reported appropriately and tracked in REDCap.

If the participant exhibits any significant or unexpected psychological symptoms, social issues, physical injuries, or medical injuries during the study the therapist/study team will talk one on one about their symptoms and continuation in the group. They will encourage participants to reach out to psych services during these one-on-one conversations. Some studies have found temporary exacerbations of PTSD symptoms and temporary increases in depression, anxiety, and sleep disturbance symptoms for a subset of participants during PTSD treatment [58, 54]. Importantly

though, for participants who saw an increase in PTSD symptoms, the increase was temporary and they still experienced clinically significant improvement by the end of treatment, indicating the treatment's safety [57]. Similarly, for those who saw an increase in depression symptoms, the increase was temporary and did not have a strong impact on the participants' treatment outcome[57]. One study did show that in rare cases, such symptoms referenced can be severe (see "Potential Risks" above for more information)[54]. Ultimately, previous studies found that although some participants may experience transient increases in mental health symptoms, like depression and PTSD related symptoms, confronting past traumas is overall still a safe and effective intervention strategy. There is an option at the end of each session for 15-20 minutes for participants to de-stress and relax if they are emotionally distressed from session content.

The study therapist or study team member will be required to track each adverse event using the adverse events tracking spreadsheet and designated follow up questions. The adverse events tracking spreadsheet will include a description of the event, start and stop date, severity grade, relatedness grade, action taken, outcome, and whether the event qualifies as a serious adverse event. The follow up questions are as follows; "How has this impacted you? (to get at severity), Has this been affected by your participation in the treatment? (e.g., is group making your experience/symptoms worse, or is this directly caused by treatment). Follow up questions will be up to the study personnel dependent upon what the participation has shared. The study team will also record the event and its details using our electronic database, REDCap. The participant may be withdrawn per the discretion of the study therapist and clinical supervisors.

Guidelines for assessing the severity and study relatedness of each adverse events will follow the procedures outlined in Schnurr et al., 2022 and collaboratively determined by the study therapist and study team.

Severity:
Mild: Does not interfere with daily functioning/normal activities
Moderate: Interferes with normal activities to some extent
Severe: Interferes significantly with normal activities

Relatedness:

1. Not attributed to a study intervention
2. Possibly attributed to a study intervention
3. Attributed to a study intervention

An adverse event will be considered associated with the study if there is a reasonable possibility that the event was caused by the treatment or by an individual's participation in the research study. Any event with a reasonable causal relationship will be considered related.

The reporting period of adverse events begins from when participants sign the informed consent form until their final study visit (3-month follow-up visit), or until participants withdraw themselves from the study, whichever is sooner. All adverse events will be tracked using the Adverse Events tracking form. When adverse events occur, we will follow the Health Sciences IRB Unanticipated Problems Reporting Decision Tree.

Data and Safety Monitoring Plan/Data and Record Keeping:

We plan to utilize the UW ICTR Data Monitoring Committee (DMC) to oversee the study across all participating sites. The UW ICTR DMC is comprised of experienced members (core plus ad hoc) with expertise required to oversee this study. The DMC members will review protocol-specific reports created by statisticians using data pulled from the Research Electronic Data Capture (REDCap) data management tool. These standard reports will include an overview of study objectives, a review of actual and projected accrual rates, an evaluation of patient demographics for balance of randomization, and a summary of the number and seriousness of adverse events. An interim analysis of study results may be requested, and source documents may be reviewed to allow the DMC to independently judge whether the overall integrity and conduct of the protocol remain acceptable based on data provided and reported by the Principal Investigator. The DMC will make recommendations to the Principal Investigator that could include actions of continuation, modification, suspension, or termination.

In providing oversight for the conduct of this study, the ICTR DMC will meet every 6 months during the 3-year study to review all adverse events. Additional meetings may be scheduled as determined by the DMC or as requested by the PI. We will submit all reportable events to the DMC and the UW-Madison HS-IRB in accordance with their reporting guidelines. Additionally, Dr. Koenigs will review weekly progress reports that characterize the overall quality of each session and any unexpected events.

Data from this study will exist in a combination of electronic (computer) and paper files. We will use ICTR's instance of REDCap to support electronic data collection and storage. Data will be collected primarily on the REDCap Mobile App, a highly secure application that provides the ability to collect data offline. Offline data collection is required because of a lack of internet access at each prison. The REDCap Mobile App requires users to enter a username and unique pin to access the project, and data is encrypted on the device's hard drive. Data collected on the REDCap Mobile App will regularly be removed from the mobile device through transmission to the project's REDCap server. To protect the confidentiality of the electronic information, all electronic data will be coded, and the REDCap data collection project will not be stored with any personally identifying information. The code file with identifiers will always be stored separately from the coded electronic data under password protection.

Data collected on paper forms will be entered through REDCap's web-based application and stored on the project's REDCap server. The paper files will be coded, such that only a five-digit numerical code (not identifiable information such as the participant's name or birth date) will appear on the paper files. The paper files (i.e., questionnaires) will be stored in a locked file cabinet at the facility, only accessible by the DOC study therapists. At midpoint data collection, research staff will transfer the paper data from the first 6 sessions to a cabinet in a locked office in the P.I.'s laboratory in the Department of Psychiatry or locked filing cabinet in the Department of Psychology. At post-test data collection, research staff will transfer the paper data from the following 6 sessions to a cabinet in a locked office in the P.I.'s laboratory in the Department of Psychiatry or locked filing cabinet in the Department of Psychology. Access to the locked offices/cabinets will be limited to the members of the study team listed in this application.

The CAPS-5, treatment sessions, post-treatment focus groups (NIMH Branch), and post-treatment individual interviews (WPP Branch) will be recorded using DOC-approved digital audio recording devices. Audio recording devices will be password protected. Electronic data will be stored on a secure departmental server that is HIPAA compliant. To protect the confidentiality of the electronic information, all electronic data will also be coded, so the participant information will not be stored with any personally identifying information. The code file with identifiers will always be stored separately from the coded electronic data. The code file will be encrypted using a commercially available encryption program. The file will be unreadable without the encryption key. Therefore, even in the unlikely case that the files were somehow accessed inappropriately, the identifiable participant data would still be protected by the encryption. Hard copies of the encryption key for the code file will be stored by Dr. Koenigs (in a locked cabinet in his locked office) and by the Department of Psychiatry IT staff (in a locked cabinet in a separate locked office).

Study staff will use a HIPAA compliant UW-Madison Secure Zoom account to conduct virtual assessments. For these virtual visits, correctional staff will escort the participant to the private testing room but will not be present during the assessment.

Unspecified Future Research

The study data will be used only by Dr. Koenigs' research team at UW-Madison. Only the UW-Madison study team personnel listed in this application will have access to the participant identifiers. The study data will be stored indefinitely in the database described in 2014-0350. Participants will have the option, at the time of consent, to give their permission to share data in the case of unspecified future research. Data will only be shared for future use with UW-Madison affiliates. We will not share data with any other companies or organizations, and any data that is shared will be stripped of identifiers.

Data that may be used for future research includes all symptom outcome measures collected throughout this study, and if a participant completed the CPT group. This data will be added to our current approved database protocol (2014-0350). The following information is included in this protocol, and applies to our future use of the data collected in this study:

> #2014-0350: This project will involve no procedures or interventions. There will be no interaction with participants. This application is for the creation of a database only.
>
> The database will be used to identify characteristics of incarcerated individuals (e.g., personality traits, mental health diagnoses, cognitive test scores, demographic data, etc.) that relate to criminal behavior. We will also use the database to retain the names of residents who have agreed to be contacted for future research studies. Dr. Koenigs will be the P.I. on any future studies that use data from this database, as well as on studies that contribute data to this database.
>
> The data from this database exist in a combination of electronic (computer) and paper files. The electronic data are stored in single encrypted spreadsheet file, which will be stored on a secure password-protected Department of Psychiatry server. The paper files

will be stored in a locked cabinet in a locked office in the P.I.'s laboratory. To protect the confidentiality of the database information, all participant data will be coded, so the participant information will not be stored with any personally identifying information. The key that identifies individual participants will be encrypted and stored separately from the database file. All paper study data (e.g., questionnaires, surveys, etc.) will be stored in locked file cabinets in a locked office. Paper study data will include codes only (no names or other identifiable information in the paper records). All electronic study data will be encrypted and stored on a secure server. Because the majority of the data included in this database contains old data (although some data will be added from studies that are currently open), and because we will take sufficient care to protect the confidentiality of the study data, we believe that the risks to participants are minimal. The potential benefit to society is considerable; by developing a better understanding of the psychological, behavioral, demographic, and environmental characteristics the contribute to criminal recidivism, this research could lead to more effective diagnostic and treatment strategies for criminal offenders.

Any individual studies that contribute to this database which are currently open for data collection will remain open for data collection, and the data will be added to the database.

Since some of the individual studies that will contribute to the database have Certificates of Confidentiality (CoC), we will obtain an amended CoC for this research database.

The data in this database will be used only by Dr. Koenigs' research team at UW-Madison to identify relationships between psychological assessment information, self-reported personality traits, and criminal history and behavior.

All future uses of the database will be submitted to the IRB. The study P.I. (Dr. Koenigs) will oversee all data transfer, storage, and analysis. Any unanticipated problems or complications will be reported immediately to the MR-IRB.

Human Participants Considerations Specific to Incarcerated Populations: Given the incarcerated status of potential participants, we outline several additional protections:

1. Potential research participants will be identified by the research team—no correctional staff will be involved in the identification of potential participants for this research study. Participants will be randomly selected from the database of residents that meet the eligibility criteria.

2. It will be emphasized to participants that participation in the study will have no effect on incarceration status, and that study results will not be shared with correctional staff. In addition, it will be emphasized to correctional staff that individual study results will not be shared with residents or correctional staff.

3. The consent, assessment and treatment will occur in a private room, without the presence of correctional officers.

4. The questionnaires and treatment protocol used in this study are common techniques for healthy populations, and do not provide any risk to residents that would not be encountered by non-incarcerated populations. We thus anticipate the creation of only minimal risk from these procedures, similar to those that would be encountered in non-incarcerated populations.

5. In this study we are enrolling incarcerated individuals who may or may not have completed high school education and may have limited reading skills. We are taking several precautions to ensure that participants in this study can understand the written consent information. To ensure that all study information is presented in language that is understandable to the resident, all consent material is written so as to be readable to an individual with a 4th grade reading level. During the consent procedure, residents are encouraged to ask the research staff for definitions of any words that they do not understand. We will exclude any participants who have an IQ below 70 or reading level below 4th grade. Thus, we can be sure that all participating residents will have sufficient reading skills to make informed decisions throughout the study procedures.

Under DHHS 45 CFR 46.306(a)(2), biomedical or behavioral prisoner research may only be conducted if the research involves specific criteria. This proposed study satisfies criterion (i) "Study of the possible causes, effects, and processes of incarceration, and of criminal behavior".

Regarding criterion (i), this study is designed to identify psychological and affective factors that may predispose a person to criminal behavior and incarceration in order to effectively design and implement treatment programs. Specifically, PTSD severity has been linked to increased risk of recidivism, and trauma is a hypothesized precursor to criminality [2,3,10].

Statistical Considerations:

NIMH Branch:
The primary goal of this study is to establish feasibility of the target intervention (CPT). Hence, we base our power analysis on the "retention" data collected Specific Aim #1 (i.e., the percentage of participants completing the CPT intervention). A sample size of n = 32 for the CPT group will provide 80% power to perform a one-sided test where the null hypothesis is 60% retention (approximately the lowest retention rate reported in previous CPT trials, versus the alternative hypothesis of 80% retention (our study goal), with a Type I error of 5%.

WPP Branch:
The primary goal of this study is to examine efficacy of the target intervention (CPT). Therefore, we will use the same target sample size (n = 32) used to establish feasibility of the target intervention, as this reflects the number of participants needed to conduct powered analyses based on the lowest retention rate reported in previous CPT trials.

Both the NIMH and WPP branches satisfy this condition with sample sizes of n = 60 for the CPT groups and sample sizes of n = 60 for control groups (WPP branch only).

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UNIVERSITY OF WISCONSIN-MADISON

Subject CONSENT to Participate in Research
And
AUTHORIZATION to Use and/or Disclose Identifiable Health information for Research

Title of the Study: PTSD treatment for incarcerated men and women

Principal Investigator: Michael Koenigs, PhD (phone: (608) 263-1679), University of Wisconsin-Madison, Department of Psychiatry

Mailing Address: 6001 Research Park Blvd., Madison, WI 53719

Student Researchers: Odile Rodrik (phone: (608) 263-1679), University of Wisconsin-Madison, Department of Psychology

INVITATION

You are invited to participate in this research study about the treatment of PTSD (posttraumatic stress disorder) for people who have been in trouble with the law. PTSD is a reaction that people sometimes have after experiencing really negative and traumatic things. You are invited to take part because you have previously participated in our studies and have agreed to be contacted for additional studies. Approximately 72 individuals will participate in this study. Your participation in this research study is voluntary. If you decide not to participate, your treatment at this institution will not be affected in any way.

The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the study. It also explains how health information will be used for this study and for other research in the future, and requests your authorization (permission) to use your health information. Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. When we have answered all your questions, you can decide if you want to be in the study. This process is called “informed consent.”

Funding for this study is provided by the National Institutes of Health.

A. WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of the research is to learn more about how to treat PTSD in incarcerated individualsthroughout several Wisconsin prisons. Researchers at the University of Wisconsin–Madison are conducting the study. Many people in prison have experienced trauma, but very few people in prison have access to PTSD treatment, called Cognitive Processing Therapy (CPT). This research will help identify if a PTSD treatment group that is used in community settings is helpful in reducing PTSD symptoms among people who are incarcerated. The goal of CPT is to create a space for people to modify unhelpful beliefs related to trauma.

B. WHAT WILL MY PARTICIPATION INVOLVE?

If you decide to participate in this research, you will be asked to complete an interview to determine if you are currently experiencing symptoms of PTSD. If you are experiencing symptoms of PTSD, you may be invited to participate in a 6- or 12-week therapy group.

If you agree to participate, you will be included in a treatment group. The treatment group will focus on talking about how past experiences (for example, traumatic experiences) may have affected the way you think, act, and feel. The groups will meet for 120 minutes, over 6 to 12 weeks, depending on session frequency. There will be up to 10 group members in each group. In addition to the treatment sessions, group members will be asked to complete weekly "homework" worksheets to help build the skills talked about in the group. The treatment session will be led by a masters level clinical student or community provider with masters-level training in clinical psychology or social work or certification as a peer specialist.

You will also be asked to fill out questionnaires about how you are feeling (e.g., your mood, PTSD symptoms), and your experience in the group. You will complete these questionnaires on five separate occasions: once before the treatment group starts, once during the treatment group, once one week after the treatment group ends, once a month later, and once three months later. Some sessions will take place in person and some session may take place over Zoom. The questionnaires will take around 20 minutes to complete each time, and can be completed at your own pace with a tablet. A study team member can also read the questionnaires aloud, and record your answers. The week after the treatment group ends, a study team member will lead a group conversation for approximately 2 hours where you will be asked about what you liked or didn't like about the treatment. Finally, when the treatment group ends, you will also be asked to complete an interview about your current PTSD symptoms. As part of the study we will collect audio recordings of the therapy groups, interviews, and group conversation. The recordings will be used by a UW-affiliated doctor (psychologist) to check the therapists' skills and their ability to run the groups, or by a study team member to make sure the study team are assessing PTSD symptoms the correct way. Recordings will be not be shared with anybody else. Recordings will also be used to make sure we keep track of everything that participants liked or didn't like about the treatment groups. Recordings will be destroyed when the study is finished.

None of this information will be added to your medical records or institutional files. A general group note will be made to document the material covered in each treatment group, and to keep track of attendance and homework completion. No specific information about group members will be included in this note and this information will not be added to your records.

The other data collected in this study may be stored without an end date in a database that will allow us to compare your data with data from other incarcerated individuals. If you have participated in our research in the past, this database will include other information about you that we have collected from other studies. The information we store about you will not include your name. Instead, we will code your data with a five-

digit number.This number will be linked to your name, but only study researchers will be able to connect your name and your unique five-digit number.

C. HOW WILL WE USE YOUR PERSONAL HEALTH INFORMATION (PHI)

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the followingkinds of PHI:

Results of tests or procedures done as part of the study
Things you tell the research team about your physical and mental health

D. IS BEING IN THIS STUDY DIFFERENT FROM MY REGULAR HEALTH CARE?

If you take part in this study, the main difference between your regular care and the care provided through this research study is that this study is focused on PTSD symptoms. You may be able to get PTSD treatment on an individual basis with Department of Corrections psychologists and mental health staff, but the type of PTSD group treatment this study is using is not currently offered in Wisconsin prisons.

E. WHAT ARE MY OTHER CHOICES IF I DO NOT WANT TO PARTICIPATE?

You do not have to be in this research study to get care for your PTSD. If you decide not take part in the study, you have other choices. You may choose to talk to a Department of Corrections psychologist about your symptoms, or you may choose to take part in a different study, if one is available.

F. ARE THERE ANY BENEFITS TO ME?

You may experience an improvement in how you are feeling after completing a therapy group. However, we cannot promise this will happen. Your participation in this research study may benefit other people in the future by helping us learn more about how to treat PTSD in incarcerated individuals.

G. WILL I BE PAID FOR MY PARTICIPATION?

You will receive $5 per hour for participating in this study. If you complete all parts of the study (i.e., assessment sessions, 12 therapy group meetings), you will receive around $180. This money will be deposited into your account through the DOC.

H. WILL BEING IN THIS STUDY COST ME ANYTHING?

There will be no cost to you for the group therapy sessions and assessments that are part of this research study.

I. ARE THERE ANY SIDE EFFECTS OR RISKS TO ME?

Some subjects may find the paper-and-pencil questionnaires to be boring or tiring,and you may feel uncomfortable with sharing information about your emotions and personality.

During the therapy groups, some people may feel upset or emotional talking about

their feelings and experiences with others. Also, you may experience a temporary increase in feelings of depression, trouble sleeping, anxiety, unwanted thoughts or memories of the event, negative changes in your thinking or mood, avoidance, and changes in your physical or emotional reactions. If you experience increases in these mental health symptoms during treatment, please let the study therapist know.

One other risk of taking part in this study is that your study information could become known to someone who is not involved in the study. For instance, someone might find out that you have a history of trauma. If this happens, it could result in damage to your reputation or be embarrassing. Breaking confidentiality in this way could happen if any of the data we collected were to be lost or stolen from the laboratory or if any data stored in the electronic database were damaged.

J. HOW WILL MY PRIVACY BE PROTECTED AND WHO WILL USE MY HEALTH INFORMATION?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission. To protect your personal information, we use numbers instead of your name on all materials. Your name never appears in the same place as your responses. In order to keep correct records of participation, we must keep a key that allows us to link your identification code back to identifying information (i.e., names), but this key is stored in a secure place at our university. To protect your privacy, we keep these numbers and your responses separate at secure locations at the University of Wisconsin-Madison. **We will contact the prison and/or DOC (and confidentiality will be broken) only under three conditions: (1) If you tell us that you plan to hurt yourself or someone else; (2) if you tell us that you plan to escape or start a prison riot; or, (3) if you report any sexual activity or sexual assault between resident or between residents and staff. Otherwise, we will not share your information with anyone, including other residents, prison staff, or other authorities.**

We will ask you questions about depression, including thoughts and plans to harm yourself intentionally, throughout this study. If you report current plans to harm yourself, we will need to break confidentiality to let the psychologist at the prison know. If this occurs, we will talk to the psychologist right away. Mental health services at the prison will then follow up with you. If you report significant symptoms of depression, we will refer you to mental health services in the institution.

However, we cannot promise complete confidentiality. Federal or state laws may require us to show information to university or government officials responsible for monitoring the study.

The information collected from you during this study will be used by the researchers and research staff of the UW-Madison and its affiliates (the University of Wisconsin Hospital and Clinics and the University of Wisconsin Medical Foundation) for this study. It may

also be shared with others at the UW-Madison and outside the UW-Madison.

Others at UW-Madison and its affiliates who may need to use your health information in the course of this research:
• UW-Madison regulatory and research oversight boards and offices
• Accounting and billing personnel at the UW-Madison
• The National Institutes of Mental Health, the study sponsor
• Federal research oversight and regulatory agencies

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

K. WILL INFORMATION FROM THIS STUDY GO I MY MEDICAL RECORD?

None of the information we collect for this study will be put in your medical record.

L. IS MY PERMISSION VOLUNTARY AND MAY I CHANGE MY MIND?

Your permission is voluntary. You do not have to sign this form and you may refuse to do so. If you refuse to sign this form, however, you cannot take part in this research study. If you decide to be in the study, the researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health, or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights. It is possible that the researchers involved in this study will choose to stop the study and end your participation, even if you choose to participate today. This could happen if a safety concern associated with the treatment is identified. You will be notified if such a situation happens.

Your authorization for researchers to use your protected health information (PHI) will last until the study is done. If you participate in the data banking part of the study, your authorization for the banking does not have an end date. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.

To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher: Michael Koenigs, PhD, 6001 Research Park Blvd., Madison, WI 53719

You may completely withdraw from the study at any time. You also may choose to stop participation or skip any questions that you do not feel comfortable answering. If you withdraw, you will be paid for any tasks that you already completed, and your previous data will be included in the study. You also may be withdrawn by the study team if it is in your best interest.

IF YOU DECIDE NOT TO PARTICIPATE IN THIS STUDY OR IF YOU STOP WHILE THE STUDY IS UNDER WAY, IT WILL NOT AFFECT YOUR STATUS IN THE PRISONS OR WITH THE DEPARTMENT OF CORRECTIONS. YOUR PARTICIPATION WILL HAVE NO EFFECT ON PAROLE DECISIONS.

M. WHO SHOULD I CONTACT IF I HAVE QUESTIONS?

Please take as much time as you need to think over whether or not you wish to participate. If you have any questions about this study at any time, contact the Principal Investigator Michael Koenigs, PhD at (608) 263-1679. You can mail Dr. Koenigs at 6001 Research Park Blvd., Madison, WI, 53719.

If you have any questions about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

You can mail the UWHC Patient Relations Representative at 600 Highland Ave., G7/210, Madison, WI, 53792.

N. OPTIONAL STUDY ACTIVITIES

This part of the consent form is about additional studies that you can choose to take part in. Things to know about these studies:

- They are optional.
- You can still take part in the main study even if you say “no.”
- These studies will not help you directly, although you may experience less PTSD symptoms if you complete the treatment. We hope the study results will help other people with PTSD.
- We will not tell you the results of these optional studies, and we will not put the study results in your medical records.
- Taking part in the optional studies will not cost you

Data Storage for future unspecified research:
In the past, we have run other studies at this facility, including brain imaging (MRI) studies. If you have participated in these studies in the past, we may wish to compare your data from this study to data from past studies. If you do not give us permission to continue to store your previous data to use with these data, we will not link your data with other information, or information from other studies. Any data you provide will be coded and stored in electronic and paper form in locked cabinets and secure computers in our research facilities. The research team will maintain a link between your data and your identifiable information kept by the study team. Stored data will not be shared with your health care providers or used in your treatment outside this study. Data would be stored for research purposes only, and may be stored indefinitely.

We will store this data with other data we have collected from you throughout your participation in other studies. Because of this, loss of confidentiality is a possible risk associated with allowing us to store your data. For example, if someone broke into thelocked cabinets or hacked into the secure computers and stole this data, they would also have access to other data we have collected (e.g., about drug use). This couldpose a risk legally, or to your reputation.

If you give us permission to continue to store your previously collected study data and use it in combination with data from this study, please initial here:_____.

Data Sharing:
Data will only be shared for future use with UW-Madison students or employees. We will not share data with any other companies or organizations. Any data that is shared will not include any identifiable information about you. For example, when we give your data to other investigators for research projects, they will not be able to use the code to figure out which data are yours.

If you give us permission to share data with other researchers, please initial here:_____

AGREEMENT TO PARTICIPATE IN THIS STUDY AND PERMISSION TO USE AND/OR DISCLOSE MY HEALTH INFORMATION

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study.

If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the research team has answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

Name of Participant (please print):_____

_____

Signature of Participant Date

YOU WILL RECEIVE A COPY OF THIS FORM AFTER SIGNING IT.

Signature of person obtaining consent and authorization:

_____

Signature Date