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Study protocol: Hybrid Type I cost-effectiveness and implementation study of interpersonal psychotherapy (IPT) for men and women prisoners with major depression

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Abstract

Purpose—This article describes the protocol for a Hybrid Type I cost-effectiveness and implementation study of interpersonal psychotherapy (IPT) for men and women prisoners with major depressive disorder (MDD). The goal is to promote uptake of evidence-based treatments in criminal justice settings by conducting a randomized effectiveness study that collects implementation data, including a full cost-effectiveness analysis.

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Competing interests. The authors have no competing interests.

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Background—More than 2.3 million people are incarcerated in the United States on any given day. MDD is the most common severe mental illness among incarcerated individuals. Despite the prevalence and consequences of MDD among incarcerated populations, this study will be the first fully-powered randomized trial of any treatment for MDD in an incarcerated population.

Design—Given the politically charged nature of the justice system, advantageous health outcomes are often not enough to get an intervention implemented in prisons. To increase the policy impact of this trial, we sought advice from prison providers and administrators about outcomes that would be persuasive to policy-makers and defensible to the public. In this trial, effectiveness questions will be answered using a randomized clinical trial design comparing IPT plus prison treatment as usual (TAU) to TAU alone, with outcomes including depressive symptoms (primary), suicidality, and in prison functioning (enrollment and completion of correctional programs; disciplinary and incident reports; aggression/victimization; social support). Implementation outcomes will include cost-effectiveness; feasibility and acceptability of IPT to clients, providers, and administrators; prison provider intervention fidelity, attitudes, and competencies; and barriers and facilitators of implementation assessed through surveys, interviews, and process notes.

Keywords

Prisoners; prisons; major depressive disorder; implementation science; cost-effectiveness

1. Introduction

More than 2.3 million people are incarcerated in the United States on any given day^{1,2}. Incarcerated individuals have high rates of mental health problems³. In fact, the three largest mental health treatment facilities in the United States are correctional institutions⁴.

Major depressive disorder (MDD) is the most common severe mental illness among incarcerated individuals^{3,5,6}. A Bureau of Justice Statistics national survey of state prisoners found that 23.5% met criteria for MDD within the past 12 months, three times the national 12-month prevalence³. In addition to being the 4th specific leading cause of death and disability burden in the world⁷, MDD has serious consequences for prisoners. In-prison effects of MDD include dramatically increased risk for suicide^{8–10}, dropout from correctional treatment programs^{11–14}, rejection by other inmates¹⁵, inability to assertively protect oneself¹⁶, physical victimization by other inmates¹⁷, and aggressive acting out¹⁶. The impairment in social, family, and occupational functioning seen with MDD¹⁸ also has repercussions for individuals leaving prison as they try to re-integrate into their communities. In fact, MDD increases risk of return to correctional custody^{19–21}.

Despite the prevalence and consequences of MDD, there has never been a fully powered randomized controlled trial (RCT) of any treatment (psychosocial or pharmacological) for MDD in an incarcerated population. The largest RCT to date (n = 38) was published by the first author in 2012²². This is in contrast to the thousands of RCTs of treatments for individuals with MDD in the community (150 published in 2007 alone)²³, which may reflect a political and societal ambivalence about investments in mental health for this population.

The proposed study is the first fully-powered RCT of treatment for MDD in an incarcerated population.

Interpersonal psychotherapy (IPT) has proven effectiveness for MDD in many mental health treatment settings^{24–27}. IPT also has potential for good uptake within prison systems because it (1) is effective in a group format^{22,28}, (2) can be effectively delivered by counselors without advanced degrees^{28,29}, and (3) addresses the life stressors, relationship challenges, and social isolation that are salient among prisoners with MDD^{30–33,34}. This NIMH-funded R01 hybrid cost-effectiveness/implementation study: (1) evaluates the effectiveness of adding IPT for MDD to prison treatment as usual (TAU) relative to TAU alone among male and female prisoners from prisons in two states, and (2) collects descriptive implementation data, including a full cost-effectiveness evaluation, to inform subsequent implementation trials. There are few previous methodologically rigorous RCTs of mental health treatments for justice-involved individuals, and none addressing MDD. The integration of effectiveness, cost-effectiveness, and implementation outcomes in this trial make it noteworthy, as do prison-related implementation issues (e.g., the politically charged nature of decisions about resources for prisoners).

2. Method

This RCT (1) evaluates the effectiveness of IPT for MDD + TAU relative to prison TAU alone among a target population of 90 male and 90 female prisoners from multiple prisons across two states, and (2) collects descriptive implementation data, including a full cost-effectiveness evaluation, to set up subsequent implementation studies. Effectiveness outcomes include depressive symptoms, suicidality, and in-prison functioning (i.e., enrollment and completion of correctional programs [e.g., GED classes, domestic violence programs, job training]; disciplinary and incident reports; aggression/victimization; social support). Implementation outcomes include cost and cost-effectiveness, feasibility and acceptability of IPT to all stakeholders, prison provider intervention fidelity, prison provider attitudes and competencies, and barriers and facilitators of implementation assessed through surveys, interviews, and process notes.

The trial is funded by the National Institute of Mental Health. It is approved by Brown University's Institutional Review Board as well as regulatory bodies overseeing prison research in both participating states. A three-member external Data Safety and Monitoring Board has been assembled to evaluate data and safety of study participants. The trial is registered at clinicaltrials.gov (NCT01685294).

2.1. Rationale for Hybrid Type I effectiveness-implementation study design

Clinical effectiveness trials evaluate the outcomes of an intervention delivered in real-world settings using real-world providers. Implementation trials compare strategies for improving the uptake, fidelity, or sustainability of interventions already shown to be effective³⁵. Curran et al.³⁶ have described how trials combining elements of clinical effectiveness and of implementation trials can be used to provide “more rapid translational gains, more effective implementation strategies, and more useful information for decision makers,” improving the speed and enhancing the public health impact of research (p. 217). Hybrid effectiveness-

implementation studies vary in the degree to which they emphasize the test of intervention effectiveness (Hybrid Type I), the test of implementation strategy effectiveness (Hybrid Type III), or both (Hybrid Type II)³⁶. A Hybrid Type I study, such as this one, provides a randomized test of a clinical intervention (i.e., rigorous effectiveness trial) while gathering descriptive information to guide future implementation efforts^{36,37}. Hybrid Type I trials are appropriate when the clinical intervention appears likely to be effective using the new setting, population, or delivery method (in our case, IPT is a front-line treatment for MDD in many other populations and evidence from our pilot RCT suggests that it is likely to be effective among prisoners²²) and when the clinical intervention provides minimal risk to study participants.

In this Hybrid Type I trial, effectiveness and cost-effectiveness questions will be answered using an RCT design and data including longitudinal interview, self-report, and medical and correctional records. Implementation questions include: (1) what are the facilitators/barriers to delivering IPT for MDD in prisons using existing prison counselors, and (2) how likely is IPT to be implemented in prisons, and (3) what implementation strategies might maximize the facilitators and overcome barriers to implementation? Implementation data will consist of stakeholder (i.e., prison provider, administrator) surveys at the beginning and end of the effectiveness trial, client acceptability surveys, cost data from facilities and providers, audiotapes of intervention sessions, process notes from study clinical supervisors' meetings with study clinicians, expert ratings of intervention fidelity, and qualitative interviews with participating providers and other prison decision-makers. This data will provide a mixed-method, multi-stakeholder process evaluation of intervention training and delivery. To put it another way, in this Hybrid Type I study, participants are randomized to interventions (IPT or TAU) and there is a single implementation strategy³⁸ being tested: provider training and supervision. Therefore, this trial is simultaneous an effectiveness/cost-effectiveness RCT and an implementation strategy open trial. Assuming that IPT is found to be effective in this trial, the subsequent implementation trial will provide all participants with IPT and will compare two (or more) implementation strategies using a randomized design.

2.2. Rationale for choice of study outcomes

Societal issues strongly affect choice of outcomes in prison and jail health intervention RCTs that aspire to have real-world impact. Despite pressing public health needs and responsibilities for incarcerated individuals, unlike most healthcare systems, the justice system (including prisons and jails) has a primary goal of public safety rather than public health³⁹. The system's public safety mandate is to protect the public from harmful behavior (such as crime) and to bring individuals who violate the law to justice⁴⁰. However, federal statutes and ethical obligations⁴¹ mandating adequate medical treatment for individuals in the justice system give it a secondary public health responsibility, posing a problem of multiple (and occasionally competing) system goals^{39,42}. That public health is a secondary goal can be seen even in prison mental health and substance use treatment research, the vast majority of which examines the effects of interventions on public safety outcomes (recidivism, arrest) only, ignoring health outcomes (e.g.,^{43–46}).

Taxman and Belenko explain that a “dilemma about providing treatment to offenders is that the customers are people who have wronged society and who are being punished”³⁹ (p. 190). Offenders are often considered *lesser* citizens⁴⁷ and they have diminished civil liberties and responsibilities (i.e., limitations on voting, employment, public housing)³⁹. These factors may affect the empathy of general society toward offenders³⁹. The external community may debate whether offenders deserve evidence-based mental health care, and whether treatment services for offenders are essential or the responsibility of tax-payers³⁹. Those who make decisions about what mental health treatments will be provided in prisons need to be able to defend their decisions to politicians, legislators, prosecutors, judges, and defenders, who may have different agendas and strong opinions, and in turn, these stakeholders have to be able to explain the decisions to the public³⁹. Therefore, for results of an RCT to influence intervention adoption and sustainment in prisons, unlike RCTs in most populations, it is not usually enough to show that the intervention has advantageous health outcomes. Even sympathetic administrators and policy-makers have to defend treatment decisions in the wider political arena, which is often less sympathetic.

Given this larger societal context, we sought advice from prison providers and administrators about additional outcomes that would be persuasive to policy-makers and defensible to the public. These included reduced suicidality, disciplinary and incident reports, and aggression/victimization (each of these create hassle, cost, and liability risk for prisons), and increased enrollment and completion of correctional programs, such as GED classes, domestic violence programs, or job training programs. Cost-effectiveness (and particularly cost-offsets that may come from reductions in discipline reports, hospitalization, etc.) may be the most important outcome for eventual implementation: cost-benefit and reinvestment frames for justice-related issues test strongly with voters⁴⁸.

2.3 Preliminary studies

Preliminary studies included two open trials^{29,49} and a pilot randomized trial²² of adaptations of IPT for women prisoners with MDD, as well as mixed method studies with study participants⁵⁰ and prison providers⁵¹ about the treatment needs of prisoners with MDD. This research indicated that MDD treatment in prisons is needed. Prisoners enrolled in the three treatment trials had severe recurrent MDD, despite the fact that a majority were taking antidepressant medications. The median number of past depressive episodes was “too many to count.” Participants were young, primarily single, and poor. Other typically negative treatment indicators, including physical (81%) and sexual abuse (78%) histories and borderline (35%) and antisocial (45%) personality disorders, were common.

Our pilot trials also showed that group IPT for MDD was feasible and acceptable, and likely efficacious among women prisoners, and that prison participants and providers viewed it as relevant and important. After the first open trial demonstrated feasibility and acceptability⁴⁹, the pilot randomized trial (n = 38)²² found that IPT resulted in lower depressive symptoms and greater decreases in interpersonal problems than did an attention-matched psychoeducation control condition. Pilot RCT findings were also notable because study treatment doses were small relative to the other services participants were receiving at the prison, including residential substance use treatment (for all women), individual mental

health counseling (for some women), and antidepressant medications (for many women). In fact, IPT produced better MDD outcomes despite patterns of medication use and other mental health treatment that should have biased the study in favor of the control condition²². Pilot RCT procedures resulted in good treatment and study retention rates. Follow-up qualitative interviews and surveys with study participants⁵⁰ indicated that participants viewed the interpersonal issues addressed in IPT as vital to their well-being and that a mean of 13 months after release from prison, they viewed IPT depression treatment as the most important treatment they received in prison. A survey of prison providers, administrators, and stakeholders (n = 17) indicated that they viewed treatment focused on relationship issues (IPT addresses relationship issues) as the most important kind of treatment for women to receive in prison (9.3 out of 10), with treatment for MDD coming as a close second (9.2 out of 10).

The second open trial²⁹ also demonstrated that bachelor's level prison counselors who are not licensed or license-eligible mental health professionals can deliver IPT adherently and competently. In many prisons, specialized mental health professionals (e.g., MSWs and PhDs) are in short supply. Therefore, after initially piloting group IPT using co-therapist teams consisting of non-specialist bachelor's-level prison counselors and psychology postdoctoral fellows^{22,49} we explored an alternative task-shifting approach. We trained additional prison counselors who were not mental health treatment specialists. These counselors were re-entry workers (i.e., bachelor's level counselors who helped to coordinate services and logistics for individuals leaving prison) and a bachelor's level prison substance use counselor from women's prisons in two states. These individuals were selected to determine whether counselors with bachelor's degrees could deliver group IPT adherently and competently without cotherapists. Although the non-specialist counselors responded enthusiastically to the treatment, they asked for more detailed information on some treatment elements than was described in published IPT manuals^{52,53}. We created a training manual that explained the essential elements of IPT in more detail and with less jargon for these counselors, with extensive input from them to make sure all sections were clear and simple to understand. Our second open trial (n = 22) found that these counselors were able to conduct IPT adherently, competently, and effectively using the expanded training manual²⁹. Based on these pilot studies, we designed the current trial to examine the effectiveness, cost-effectiveness, and implementability of IPT for MDD, delivered by prison counselors with a range of previous mental health treatment training, for men and women in prisons across two states.

2.4. Interventions

2.4.1. Rationale for IPT + TAU vs. TAU alone design—*The purpose of the trial is to inform prison practice and policy.* According to NIMH's Road Ahead report, "policy makers need to know if a new program works better or costs less with similar effectiveness than what is currently available, or if it is better than doing nothing at all" (p. 10). In some cases, the important question for implementation is: "how much better is the new program than care-as-usual and at what cost?" (p 11).⁵⁴ Furthermore, because external validity is such a salient concern in criminal justice settings, many, if not most, NIH-funded criminal justice R01s use TAU controls (i.e., MH094090, MH086232, MH088716, DA025943,

DA027209, DA021174, DA018977). Because our goal is to design a study that is most relevant to prison policy decisions, we decided to employ a treatment as usual (TAU) control condition. In order to determine the naturalistic effects and costs of adding IPT to the prison setting, participants in both conditions can receive any other treatment available to them and we will not exclude participants receiving other treatment, including antidepressant medications. We will carefully characterize prison TAU separately for each condition as part of our effectiveness and cost analyses because it is likely that IPT participants will use less TAU. Because this is an intent-to-treat trial in a real-world setting, participants will *not* be discontinued from the active treatment phase or from the study for study treatment non-participation.

2.4.2—IPT + TAU participants will receive standard group IPT, as specified in the training manual and published IPT manuals^{52,53}, in addition to prison TAU. IPT focuses on addressing recent life stressors in the context of building or better utilizing one's social support network. IPT identifies a current interpersonal crisis in one of four areas (interpersonal conflict, life change, grief, social isolation) as the proximal trigger for the current depressive episode and addresses it by helping the individual to improve communication, change relationship expectations, or adapt to changes within the context of building or better utilizing a social support network^{52,53}. This approach is relevant to the treatment needs of prisoners with MDD, for whom life stressors, relationship challenges, and social isolation are common and salient^{30–33,34}. The therapeutic stance of IPT is active, goal-oriented, semi-structured, supportive, positive, present-focused, and conducive to skills acquisition. IPT participants will receive 20 90-minute group therapy sessions over 10 weeks and 4 individual (pre-group, mid-group, post-group, and maintenance) sessions. The maintenance session occurs 4 weeks after the post-group session. The individual sessions were used successfully in our pilot work and in other group IPT protocols⁵³ to prepare patients to use the group effectively and to keep group members focused on their interpersonal goals.

2.5.2. TAU alone—Participants in this condition will be screened and offered referrals to prison mental health staff for TAU. Nationally, TAU for MDD within prisons typically consists of antidepressant medications (either tricyclics or SSRIs)⁵⁵, with about 80% of inmates being treated for MDD in one large state being given antidepressants⁵⁶. Compliance with these medications is reasonable (75–80%)⁵⁵. Limited psychosocial treatment (e.g., psychoeducation, once-monthly check-ins with a mental health clinician) is available for some. Criteria for being offered prison mental health services (medications and/or psychosocial treatment) vary by facility. In addition, some prisoners with MDD choose not to receive any treatment because they do not find medications or the psychosocial intervention offered acceptable. . No one other than individuals employed by our studies currently provides IPT within participating facilities.

2.6. Power

Our pilot RCT indicated an effect size for IPT relative to psychoeducation of $d = .70$ (95% CI = .03 1.33) for depressive symptoms (Hamilton Rating Scale for Depression [HRSD] scores⁵⁷) at the end of prison group treatment. Both treatments occurred in addition to prison

TAU. In previous randomized trials, intent-to-treat effect sizes (Cohen's d) of IPT relative to placebo for HRSD depression scores have been .44²⁷ and .43⁵⁸. Intent-to-treat effect sizes of IPT + medications vs. medications alone have been .37⁵⁹ for depressive symptoms and .35⁶⁰ and .73⁶¹ for dichotomous outcomes. This study is powered to detect an effect size at the lower end of the range of effect sizes of successful similar studies, or a $d = .37$. Using standard deviations from our pilot data, an effect size of $d = .37$ corresponds to a difference between conditions of 4.5 scale points (out of 54) on our depression symptom measure (HRSD). Given that non-inferiority limits for the Hamilton have been set at about 2.5 points⁶² and the NICE guidelines consider a 3-point difference between conditions to be the cutoff for clinical significance⁶³, the 4.5 point difference is near the minimum clinically significant difference between groups.

After examining a range of plausible effect sizes and attrition rates (see Table 1), we decided to base our power analyses on a 10% attrition rate over the 6 months from baseline to 3-month follow-up. A 10% attrition rate is low compared to some studies, but reasonable in this study because: 1) Follow-up interviews take place inside prison; and 2) our previous treatment studies with prisoners have had 90%–100% rates of completion for 3–6 month follow-ups that took place in the community after prison release due to careful, diligent tracking of participants^{22,64}. It is highly likely we can do at least that well with in-prison follow-up.

2.7. Research sites and randomization

Study participants will be recruited from the women's facilities and from men's medium security facilities in two northeastern U.S. states. These facilities house the entire female state prison populations for both states, all the medium security men in one state, and part of the medium security men in the other state. Prisoner demographics and sentencing practices are similar between the two states. Treatment as usual for MDD between the two states is also similar, consisting mainly of medications with occasional psychosocial treatment. Because these services are similar to other state prison facilities nationally⁵⁵, findings from this study are likely to be generalizable. To increase balance between conditions, randomization will be stratified by state and by sex (male or female).

2.8. Participants

Participants will be sentenced prisoners between the ages of 18 and 65 who are incarcerated in one of the participating prisons. Participants must also: (1) Meet DSM-IV-TR criteria for current primary (non substance-induced) MDD after at least 4 weeks incarceration and abstinence from substances. (2) Be likely to stay at their current facilities for at least 6 months, giving us time to complete the treatment and follow-up phases. Individuals who meet lifetime criteria for bipolar disorder or a primary psychotic disorder or who cannot understand English well enough to understand the consent form or assessment instruments when they are read aloud will be excluded. Virtually all men and women at participating prisons speak English. Consent forms will always be read aloud. We will also offer to read each questionnaire aloud.

We will take several steps to avoid coercion in the consent process. Prior to enrolling each participant in the research, research staff will fully explain the study procedures, risks, benefits, and alternatives. Research staff will emphasize that choosing to participate has no effect on the other services individuals will receive at the prisons or the terms or length of their confinement, and neither does choosing not to participate or withdrawing from the study. All reimbursements for participating will be commensurate with participants' time required for participating in the research. Participants also complete a short (5-item) questionnaire covering basic elements of study participation, which research staff review with them to clarify any potential misconceptions.

2.9. Counselors

IPT counselors in the current study will be counselors employed at participating prisons, with a bachelor's degree and at least one year of experience working with incarcerated individuals. As in our previous studies^{22,29,49}, some study counselors will have advanced degrees in mental health fields with previous mental health treatment training, and some will not. Implementation outcomes, including treatment integrity (rated by independent raters), cost and time involved in the training, and any retraining/extra supervision required, will be collected as part of the training process. We will explore how these vary by provider mental health training. One of the implementation barriers for evidence-based mental health treatments in prisons is not having enough trained mental health providers to serve all the need⁵¹. Therefore, to explore whether a task-shifting approach is feasible and effective, this trial will explore intervention fidelity and outcomes obtained when bachelor's level providers who are not mental health treatment specialists are used as service extenders, and whether they are more or less expensive when the supervisory time and effort to train them is taken into account.

The principal investigator, who is a certified IPT supervisor, will train counselors in IPT using the training manual, which has been elaborated for bachelor's level prison counselors from other IPT training materials^{53,65} and pilot tested in our second open trial²⁹. The 2-day training consists of reviewing the treatment rationale, concepts, materials, and strategies; audio-taped demonstrations; and live practice sessions along with feedback. The PI will serve as primary clinical supervisor for study counselors, with help from other trained IPT supervisors. As in our previous IPT studies, supervision throughout the study will involve weekly review of therapists' audiotaped sessions, weekly individual phone consultation, and 2-hour in-person group meetings every 2 months. Because this trial examines real-world effectiveness and implementation, because it uses a group intervention, and because the trial is complex and the timeline tight, it is not practical to have study counselors complete IPT practice cases before treating study participants. Because some data suggest that novice IPT counselors improve significantly after their first IPT case⁶⁶, we will explore differences in intervention fidelity and outcomes between each counselor's first IPT group (when s/he is using IPT for the first time), and his/her subsequent groups.

2.10. Assessments

Participants will be assessed three times: pre-treatment, at the end of group (10–12 weeks later), and then at 3-month follow-up (about 6 months after intake; see Table 2). Participants

will receive \$10 US deposited into their inmate accounts for completion of the post-group and follow-up assessments. Assessments will take place in prison, will include structured interviews and self-report measures, and will be conducted by research assistants (RAs) with a BA or MA and experience working with individuals who are justice-involved and/or who have mental health problems. RAs will be trained in interviewer administered instruments at Brown's Clinical Assessment and Training Unit. The PI and a clinical interviewing trainer will supervise the RAs. Assessments will be audio recorded and checked for interview fidelity and quality. Twice a month, assessment trainers will choose a recently recorded interview for all interviewers to rate to check reliability, provide ongoing training, and prevent rater drift. RAs will be blind to treatment assignment.

2.10.1. Diagnosis and Screening—Participants will be asked for demographic information, arrest and sentencing history, and current psychiatric medications. The mood disorder module and psychotic screener from the Structured Clinical Interview for DSM-IV (SCID)⁶⁷ will be used to determine diagnostic eligibility. During the follow-up period, the Longitudinal Interval Follow-up Examination (LIFE)⁶⁸, a brief standardized interview, will be used to assess MDD diagnosis. Unlike the SCID, which provides only a cross-sectional measure, the LIFE tracks MDD severity and course over time. The LIFE uses Psychiatric Status Ratings (PSRs) to measure MDD severity (by number of diagnostic symptoms experienced) each week on a scale of 1 (asymptomatic) to 6 (incapacitated). MDD recovery is defined as a PSR of 1 or 2 for 8 consecutive weeks⁶⁹. The LIFE is a well-validated, widely used retrospective measure, developed for longitudinal studies, which uses a systematic calendar-based inquiry method to cue recall.⁶⁸ For example, the PSR method was used in NIMH's Collaborative Depression Study and others with good interrater reliability^{70,71}.

2.10.2. Effectiveness Outcomes. 1—*Depressive symptoms* (primary) will be assessed with the Modified 17-item Hamilton Rating Scale for Depression (HRSD)⁵⁷, a well-validated and reliable⁷² 17-item measure used extensively in MDD treatment studies⁷³ and in our prison pilot studies. **2. *Suicidality*** will be assessed with the Beck Scale for Suicide Ideation (BSS), a 21-item self-report questionnaire with excellent internal and interrater reliability⁷⁴. The BSS assesses current suicide ideation. However, our experience has been that many individuals in prison under-report current suicide ideation because suicide watch in prison is unpleasant. Therefore, we will also assess weeks of suicide ideation during each follow-up period using the LIFE (past suicide ideation does not require mandatory reporting to the prisons), and we will also assess hopelessness, which is strongly related to suicidality, using the Beck Hopelessness Scale (BHS)⁷⁵.. BHS scores have been found to predict subsequent death by suicide⁷⁶. **3. Most *in-prison functioning*** variables (e.g., number of correctional programs begun, number of correctional programs completed, number of disciplinary and incident reports) will be assessed through self-report and cross-checked against correctional records. Aggression and victimization will be measured using the reliable and valid 39-item Conflict Tactics Scale²⁷⁷ with adaptations to ask about incidents in relationships with anyone over the past 3 months, rather than only with romantic partners. Social support will be assessed with the reliable and valid 12-item Multidimensional Scale of Perceived Social Support (MSPSS)^{78,79} and the 10-item UCLA

Loneliness Scale⁸⁰. **4. Exploratory.** Given growing evidence that IPT may be effective for posttraumatic stress disorder (PTSD)⁸¹, we will explore the effects of IPT on PTSD symptoms, which are common among prisoners, using the reliable and valid PTSD Checklist Civilian Version⁸²

2.10.3. Implementation outcomes—4. Cost-effectiveness of group IPT and of TAU for MDD. Our grant accounting will capture the costs of the IPT providers as well as costs incurred to train and supervise them. We will track treatment received as part of TAU for the IPT + TAU and TAU conditions separately. Tracking the cost of TAU (both usual mental health treatment and associated medications) is easy because all prison medications and providers are paid through a single entity in each state. We will use budget data from these agencies to add fringe benefit and overhead costs to payroll costs and administrative overhead costs to contract provider costs. All costs will be converted to same-year dollars. Costs (and savings) in future years will be discounted to present value in the year of treatment initiation using the 3% discount rate recommended by the Panel on Cost-Effectiveness in Health and Medicine⁸³. If IPT is effective at improving prisoner behavior, it may lead to earlier release for some offenders and a reduction in in-prison incidents that result in new charges that extend stays. We will capture budget data on average total cost per prisoner-day that can be used to evaluate any savings of this nature. We will exclude research costs because these would not be incurred if IPT were standard care.

5. Feasibility and acceptability of IPT to all stakeholders. We will track participant feasibility and acceptability parameters including rates of treatment attendance, rates of treatment completion, reasons for termination, and treatment satisfaction. **6. Provider parameters** will include *prison provider intervention fidelity* and time/training required to achieve fidelity, number of providers who leave the prison systems during the study or who drop out of the study for other reasons and have to be replaced. We will use provider fidelity (i.e., adherence and competence) scales adapted from standard IPT fidelity scales⁸⁴ in our pilot RCT for use in groups and in prisons. Two trained expert raters will review audiotaped sessions and will provide session-level fidelity ratings. **7. Prison provider and administrator attitudes and competencies** (see Table 3). Assessments will include the Stakeholder Acceptability Survey (SAS), based on the “Awareness and Concern” and “Rogers’s Adoption Questions” items from Steckler (1992)⁸⁵. The SAS will assess ease of delivering IPT, the perceived helpfulness of IPT, and level of enthusiasm for IPT. The SAS will also assess issues related to sustainability including whether or not respondents would continue to use IPT outside of research, how easily IPT integrates into their other clinical care, and their perception of the time versus benefit trade-off for getting trained to deliver IPT. We will also assess prison provider attitudes toward evidence-based practice using: (a) the revised Evidence-Based Practice Attitude Scale (EBPAS-50), which has good reliability and factorial validity⁸⁶; (b) prison provider attitudes toward rehabilitation and punishment using an established measure adapted by Taxman from Cullen^{87–89}; and (c) provider competencies using the reliable and valid Competency Assessment Inventory (CAI)⁹⁰. The CAI evaluates the attitudes, knowledge, and skills needed to provide high-quality mental health care (e.g., learns and respects clients’ preferences about treatment, creates opportunities for clients to practice skills). These measures will be given to a variety of stakeholders, including prison

study counselors, other prison mental health providers, and prison administrators. **8.** We will examine *barriers and facilitators of implementation* using surveys, interviews, and process notes. We will use the Dimensions of Organization Readiness Revised (DOOR-R) survey⁹¹ to assess the perceived importance of intervention characteristics for implementation in these settings and how well stakeholders perceive that IPT fits each of these characteristics. We will also have brief structured interviews with prison stakeholders and study counselors. Finally, we will qualitatively analyze process notes from study meetings (including supervision sessions with study counselors, and comments on barriers and facilitators provided by fidelity raters) for information on implementation barriers and facilitators. This information will be used to determine which implementation strategy or strategies might best capitalize on facilitators and overcome barriers to implementation, so that we can test these strategies in a subsequent implementation trial.

2.10.4. Characterization of TAU (both conditions)—We will track psychopharmacological and psychosocial treatment received by participants (e.g., type, number of visits, dose, etc.) using the LIFE. We will cross-check this self-report data against correctional medical record review and report concordance.

2.11. Data Analysis

Primary analyses will be *intent-to-treat* and we will examine dose-response effects in secondary analyses. All primary tests will be two-sided with $p=0.05$. Descriptive statistics will include effect sizes and measures of clinical significance (i.e., number needed to treat; NNT) for all major comparisons. We will separate our primary hypothesis from the remaining hypotheses.

2.11.1. Missing data—We will employ multiple imputation to deal with missing data; this method takes into account the associations between observed variables and patterns of missingness^{92,93}. We will also compare treatment conditions on rates of missingness and time to missingness. We will test whether baseline characteristics are associated with missingness. Finally, we will perform a sensitivity analysis in which we impute a return to baseline levels for missing data to determine the sensitivity of analysis results to missing data.

2.11.2. Preliminary analyses—We will examine the distribution of our key variables for skewness, variability, missing data, and outliers. Preliminary analyses will also compare participants from various prison facilities on demographic and background information, parameters of study treatment and TAU received, adherence and competence rates, and treatment response. We will also check for site effects with each specific hypothesis by including site as main effect in analyses. If site differences are non-significant, they will be removed. Analyses will adjust for baseline levels of dependent variables but will not test for or adjust for any other baseline differences between conditions that result from randomization. We will evaluate the effects of non-IPT treatment on study outcomes as well as the effects of randomization to IPT on use of non-IPT treatment in secondary analyses. Reliability of adherence and competence ratings for the current study will be assessed by

computing intraclass correlation coefficients between raters of the scales. Both individual item correlations and total intraclass correlations will be calculated.

2.11.3. Analysis of effectiveness outcomes

Primary: We will test the hypothesis that, relative to TAU alone, IPT + TAU will result in lower depressive symptoms (HRSD scores) at post-treatment and follow-up, using hierarchical linear modeling (HLM) with baseline HRSD score as a covariate.

Secondary: Correcting for multiple comparisons, we will test the hypotheses that, relative to TAU alone, IPT+TAU will result in lower levels of suicidality (BSS scores, Beck Hopelessness Scale scores, weeks of suicide ideation) and better in-prison functioning, including separate tests for enrollment in more correctional programs, completion of more correctional programs, fewer disciplinary and incident reports, lower levels of aggression (CTS2 aggression score), lower levels of victimization (CTS2 victimization score), and higher social support (MSPSS scores)/less loneliness (UCLA Loneliness Scale scores). For normally distributed variables, analyses will use HLM with baseline scores as covariates. For count data, analyses will use Poisson-class regression methods^{94,95} (e.g., zero-inflated negative binomial regression) and will include appropriate tests for zero-inflation and over-dispersion. Baseline scores will be predictors in both continuous and zero-inflated models.

Exploratory: We will explore whether conditions differed in time to recovery from a depressive episode (defined as 8 consecutive weeks of a PSR of 1–2 on the LIFE⁶⁹) using Cox regression. Growing evidence indicates that IPT may be effective for posttraumatic stress disorder (PTSD).⁸¹ Therefore, we will also explore the effects of IPT on PTSD symptoms, which are common among prisoners, using the PTSD Checklist Civilian Version⁸².

2.11.4. Analysis of implementation outcomes

Cost and cost-effectiveness: Treatment costs tend to be skewed with long right tails. Therefore, we propose to rely on regression analysis to estimate the mean and standard deviation of the cost difference between IPT + TAU and TAU alone. Popular methods for dealing with skewed cost data include Ordinary Least Squares on log of costs, alternative weighting approaches based on Generalized Linear Models or exponential conditional models (ECM) with log link, and survival models. We will use the Generalized Gamma Model⁹⁶ which implements a consistent evaluation strategy of these competing methods. We will analyze costs separately by gender (and possibly facility size) because treatment needs tend to differ by gender and the larger facilities typically used to house men may benefit from cost-reducing economies to scale. If it seems helpful, we also are prepared to use Glick et al.'s⁹⁷ improved parametric representation of cost data, for example in valuing depression costs.

We will use a comparative cost effectiveness (CE) analysis of IPT + TAU relative to TAU. The primary analysis will include costs related to IPT delivery but not development. Thus it will compare cost and quality of an operational program. Secondary analyses will evaluate training and supervision costs and estimate the budget impact of newly implementing IPT

for MDD in a prison system. The primary effectiveness measure is the HRSD depression score with disciplinary infractions, suicidality, and possibly early release/added time as a result of in-prison infractions or completed prison programs as secondary measures. Following recommendations from the Panel on Cost-Effectiveness in Health and Medicine⁸³ and Neumann⁹⁸, baseline analyses will adopt a societal perspective, considering all economic costs regardless of source. We will also calculate cost per disciplinary infraction avoided from the state government's perspective, excluding benefits to the prisoners. We describe our statistical plan for determining mean change in and standard deviations of these measures above.

The CE ratio equals C/E , where C is the difference in mental health treatment costs between IPT + TAU and TAU alone and E is the difference in the outcome measure. We will compute 95% confidence intervals around the CER and test the hypothesis that the ratio is greater than 1.0. In sensitivity analyses, we will examine the CER at 0%, 1% and 5% discount rates.

Other implementation outcomes (feasibility and acceptability of IPT to all stakeholders, prison provider intervention fidelity, prison provider attitudes and competencies, stakeholder perspectives on barriers and facilitators of widespread implementation) will be examined descriptively. Qualitative data (qualitative interviews, process notes) will be analyzed using thematic analysis.

2.11.5. Predictors/Personalization—This is one of a few RCTS of correctional mental health treatments to aim to recruit equal numbers of men and women to explore gender effects, despite recognition that clinical pictures of incarcerated men and women^{99,100}, as well as costs associated with providing services in men's and women's facilities¹⁰¹, often differ. Given the importance of gender-responsive programming for offenders¹⁰², this study will explore gender as a moderator of the effectiveness and costs of IPT relative to TAU.

We will also conduct exploratory tests self-reported number of lifetime arrests, length of current sentence, psychopathy (assessed with the Psychopathic Personality Inventory: Short Form¹⁰³), MDD severity and number of past depressive episodes, and SCID-II¹⁰⁴ assessed Borderline and Antisocial personality disorders (BPD and ASPD) as moderators, with $p < .01$ to control for Type I error. We will also examine whether minority status moderates treatment outcome.

3. Summary and Discussion

There is a great need for effective mental health care for justice-involved individuals and a relative lack of research in this area to date. The need is especially acute for research evaluating intervention effects on mental health, rather than solely criminal justice, outcomes. This protocol describes a Hybrid Type 1 cost-effectiveness and implementation study of IPT for MDD among prisoners. Effectiveness, cost-effectiveness, and implementation data from this registered randomized trial will be published following the CONSORT guidelines. We anticipate that this study, conducted by a team that is experienced

with, committed to, and enthusiastic about criminal justice research, will test the effectiveness of IPT for MDD in a prison population, will provide information about cost-effectiveness of this treatment relative to TAU alone, and will elucidate potential barriers and facilitators of implementation. This information will be used to help shape choice of implementation strategies³⁸ to test in future implementation trials (which will provide randomized comparisons of the effectiveness of strategies to foster adoption, fidelity, and sustainment of IPT and other evidence-based mental health treatments in prisons), and to use in practice to implement IPT for MDD in prisons. This line of research will help provide a foundation to speed implementation of evidence-based treatments for a severe and prevalent disorder among this vulnerable, understudied population.

Pilot work leading up to this study^{22,29,49–51} indicated that: (1) treatment for MDD is needed in prisons, (2) group IPT for MDD was likely effective among female prisoners and was feasible and acceptable to them and to their providers; (3) IPT's interpersonal approach made sense to prisoners and prison stakeholders and seemed important to them; and (4) non-specialist bachelor's level prison counselors can deliver IPT adherently and competently. These preliminary studies have prepared us to successfully conduct a large, multi-component treatment trial that takes place in many prisons across two states, and incorporate cost, medical and correctional record, stakeholder survey and interview, expert rater, and process note data.

Innovative aspects of the trial include the exploration of the use of prison counselors who do not have specialty mental health training as mental health service extenders in prisons, and the goal of enrolling roughly equal numbers of men and women prisoners to allow us to explore gender-related treatment effects. Other design strengths are that the study includes stakeholder input at all phases; accommodates prison setting and provider training, needs, and preferences; works to foster an intervention that will be financially feasible, effective, available, and acceptable; works to demonstrate a method for providing high quality services at low cost; and examines factors related to personalization (i.e., it will be one of only a few prison RCTs to have a roughly equal gender ratio). The trial was designed to maximize practice and policy impact by addressing effectiveness, cost-effectiveness, and implementation questions simultaneously and by intentionally choosing outcomes that satisfy the needs of the public health community (i.e., depressive symptoms, other clinical outcomes) and that address implementation challenges in the larger social and policy context (e.g., the politically charged nature of decisions about resources for prisoners). That this trial (in 2015) is the first fully-powered MDD treatment trial for incarcerated individuals demonstrates some of these societal challenges.

Public attitudes toward offenders translate into arrest and sentencing laws (which govern how many people enter the justice system) and into funding for offender care (given that justice system budgets are set by state and local governments). Over the past 4 decades, these forces have worked against each other: justice-involved populations (including prisons, jails, probation, and parole) have expanded exponentially (1 in 36 U.S. adults is currently justice-involved^{105,106}) and justice healthcare budgets and the formal and informal processes that should work together to support the health and rehabilitation of offenders have not kept up¹⁰⁷. As a result, justice systems care for more people with fewer resources. Lack of

resources translate into crisis-oriented environments, ongoing threat of high staff turnover, high caseloads, lack of services, and lack of time to coordinate services^{39,51} with less than optimal system-wide outcomes^{39,88,108–111}. The vast majority of incarcerated individuals will leave prisons and jails and rejoin communities that will take on the costs of their untreated behavioral health conditions. The aim of this trial is to contribute knowledge relevant to discussions about the business case for public health, especially mental health, services for prisoners.

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Table 1

Ranges of plausible effect sizes and attrition rates to guide power and sample size calculations

Sample size required for 80% power			
	<i>d</i> = .34	<i>d</i> = .37	<i>d</i> = .40
15% attrition	227	192	165
10% attrition	213	180	155
5% attrition	202	171	147

Power for n = 180			
	<i>d</i> = .34	<i>d</i> = .37	<i>d</i> = .40
15% attrition	.71	.78	.84
10% attrition	.74	.80	.86
5% attrition	.76	.82	.88

Table 2

Schedule of assessments for prisoner participants

Measure	Intake	End of group treatment	3-month follow-up
SCID	X		
Psychopathic Personality Inventory: Short Form (PPI-SF)	X		
Longitudinal Interval Follow-up Evaluation (LIFE)	X	X	X
Hamilton Rating Scale for Depression (HRSD)	X	X	X
Beck Scale for Suicide Ideation (BSS)	X	X	X
Beck Hopelessness Scale (BHS)	X	X	X
Correctional discipline, incident, and medical records	X	X	X
Conflict Tactics Scale 2 (CTS2)	X	X	X
Multidimensional Scale of Perceived Social Support (MSPSS)	X	X	X
UCLA Loneliness Scale	X	X	X
PTSD Checklist (PCL-C)	X	X	X
Client Satisfaction Questionnaire - Revised		X	

Table 3

Schedule of assessments for prison providers and administrators

	Beginning of study	End of study
Evidence-Based Practice Attitude Scale-50	X	X
Attitudes toward rehabilitation/punishment	X	X
Competency Assessment Inventory	X	X
Stakeholder Acceptability Survey	X	X
Dimensions of Organizational Readiness		X