



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.

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.

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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 problems [3]. In fact, the three largest mental health treatment facilities in the United States are correctional institutions [4].

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 prevalence [3]. In addition to being the 4th specific leading cause of death and disability burden in the world [7], 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 inmates [15], inability to assertively protect oneself [16], physical victimization by other inmates [17], and aggressive acting out [16]. The impairment in social, family, and occupational functioning seen with MDD [18] also has repercussions for individuals leaving prison as they try to re-integrate into their

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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 2012 [22]. 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 [30–34]. 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 effective [35]. 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 prisoners [22]) 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 strategy [38] 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 health [39]. 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 justice [40]. However, federal statutes and ethical obligations [41] 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* citizens [47] 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 offenders [39]. 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-payers [39]. Those who make decisions about what mental health treatments will be provided in prisons need to be able to defend their

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