

**[Project ID: IIR 14-081]**

Improving Treatment Engagement and Outcomes among Justice-Involved Veterans

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## Abstract

Approximately 146,000 Veterans are released each year from correctional settings; however, two thirds will likely reoffend and return to the justice system. Antisocial cognitions and behaviors are the strongest predictors of reoffending and are highly prevalent among justice-involved Veterans (JIVs). However, in the absence of treatments with demonstrated effectiveness with JIVs, no systematic approach to address antisocial cognitions and behaviors has been implemented in VA. Moral Reconciliation Therapy (MRT) is a cognitive-behavioral intervention that aims to reduce antisocial cognitions and behaviors. MRT has the best empirical support for reducing risk for criminal recidivism among civilian offenders, and its associated mechanisms have been linked to improvements in health-related outcomes that are also risk factors for recidivism (substance use, mental health, housing, and employment problems). However, no trials have been conducted with JIVs. Differences between JIVs and justice-involved civilians suggests prior research on MRT with civilians may not be generalizable, and prompted the VA's Veterans Justice Programs (VJP) and the developers of MRT to develop a Veteran-specific curriculum of this intervention. Testing this new MRT Veteran manual is a top priority of VJP.

Using the new Veteran-specific manual, the overarching objective of the current proposal is to implement and evaluate MRT as an intervention to reduce risk for criminal recidivism and improve health-related outcomes among JIVs in VA Mental Health Residential Rehabilitation Treatment Programs (MH RRTPs). Using a Hybrid Type 1 design, this project will test the effectiveness of MRT in a multisite RCT (Palo Alto, Little Rock, and Bedford) and conduct a formative evaluation to facilitate future implementation of MRT in VA:

**Aim 1:** A total of 365 Veterans who are being admitted to an MH RRTP, and had been arrested and charged and/or released from incarceration in the past 5 years, will complete a baseline assessment, be randomized to MRT or usual care (UC), and followed at 6 and 12 months post-baseline. **Hypotheses:** Those in the MRT (vs. the UC) condition, will (1a) have a lower overall risk for criminal recidivism; (1b) have better health-related outcomes (substance use, mental health, housing, and employment); and (1c) the effects of MRT on reduced risk for recidivism and better health-related outcomes will be mediated in part by greater likelihood of completing the MH RRTP and utilizing substance use disorder and mental health continuing care services.

**Aim 2:** Using the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework, we will conduct qualitative interviews with 6 providers and 12 patients at each study site to identify (2a) barriers and facilitators to implementation of MRT in MH RRTPs across VA, and (2b) whether and/or how to adapt MRT to be most effective with diverse subpopulations of Veterans (e.g., OEF/OIF Veterans; women; racial/ethnic minorities; those with PTSD). Given that VA has not systematically implemented interventions that address antisocial cognitions and behaviors, this project fills a substantial gap in care for JIVs in VA, and therefore has significant potential to improve the long-term health of this vulnerable population.

## List of Abbreviations

Addiction Severity Index (ASI)

Center for Healthcare Organization and Implementation Research (CHOIR)

Center for Innovation to Implementation (Ci2i)

Center for Mental Healthcare and Outcomes Research (CeMHOR)

Center of Innovation (COIN)

Collaborative Research to Enhance and Advance Transformation and Excellence (CREATE)

Criminal Thinking Scale (CTS)

Fiscal Year (FY)

Generalized Mixed-Effects Regression Models (GLMM)

Health Services Research and Development (HSR&D)

Homeless Operations Management System (HOMES)

Institutional Review Board (IRB)

International Classification of Diseases, Version 9 (ICD-9)

Intervention Coordinator (IC)

Investigator Initiated Research (IIR)

Justice-Involved Veterans (JIV)

Mental Health (MH)

Mental Health Residential Rehabilitation Treatment Programs (MH RRTP)

Mental Health Services (MHS)

Moral Reconciliation Therapy (MRT)

National Center on Homelessness Among Veterans (NCHAV)

National Institute of Health (NIH)

National Patient Care Databases (NPCD)

Office of Management and Budget (OMB)

Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF)

Organizational Readiness for Change Assessment (ORCA)

Patient Treatment Files (PTF)

Posttraumatic Stress Disorder (PTSD)

Quality Enhancement Research Initiative (QUERI)

Randomized Clinical Trials (RCT)

Rapid Response Project (RRP)

Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM)

Research and Development (R&D)

Risk-Need-Responsivity (RNR)

Scrambled Social Security Numbers (SCRSSN)

Service Directed Project (SDP)

Statistical Analysis System (SAS)

Substance Use Disorder (SUD)

Time-Line Follow Back (TLFB)

Traumatic Brain Injuries (TBI)

Usual Care (UC)

Veterans Affairs (VA)

Veterans Affairs Central Office (VACO)

Veterans Informatics and Computing Infrastructure (VINCI)

Veterans Justice Programs (VJP)

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## 1.0 Study Personnel

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## 2.0 Introduction

Veterans are a large and growing segment of offenders in the criminal justice system. US military Veterans represent 10% of those incarcerated in state and federal prisons (approximately 140,000 individuals), a rate that has increased by 71% over the past two decades.<sup>12</sup> Given that approximately 75% of the correctional population in the US is on probation or parole<sup>13</sup> and that many Veterans are arrested and charged but diverted from incarceration,<sup>76</sup> these estimates represent only a fraction of the total number of “justice-involved Veterans” (JIVs) – i.e., those detained by, or under the supervision of, the criminal justice system.

JIVs are at high risk for criminal recidivism. Approximately 146,000 Veterans are released each year from correctional settings,<sup>12</sup> and many are in a chronic cycle of contact with the legal system. Data collected by the Veterans Justice Programs (VJP)—a branch of VA Office of Homelessness, which provides JIVs with outreach and linkage to VA services—show a lifetime average of eight criminal charges among Veterans served by these programs in FY11. Furthermore, two-thirds of offenders recidivate (i.e., are rearrested, reconvicted, or reincarcerated for a new crime or violation of their parole or probation) within three years from their release.<sup>1</sup> Given that the proportion of those with a prior conviction is comparable across Veteran and non-Veteran inmates,<sup>4</sup> the rate of recidivism among JIVs is likely comparable to that in the general population of offenders.

Best practices for reducing criminal recidivism: Moral Reconciliation Therapy. Cognitive-behavioral interventions that are designed to restructure antisocial cognitions and behaviors represent best practices for reducing criminal recidivism.<sup>6,8,17,18</sup> Antisocial cognitions and behaviors are the strongest predictors of reoffending<sup>3,19</sup> and are highly prevalent among JIVs.<sup>20-23</sup> The VA has not systematically implemented an intervention to address antisocial cognitions and behaviors. The VJP has highlighted this as a significant gap in care for JIVs.<sup>42</sup>

Moral Reconciliation Therapy (MRT) is a cognitive-behavioral intervention that aims to reduce antisocial cognitions and behaviors,<sup>4</sup> and has the best empirical support for reducing criminal recidivism among civilian offenders.<sup>23</sup> MRT is a manualized intervention consisting of open-enrollment group sessions that move participants through 12 steps. The curriculum was designed to be appropriate for those with lower reading skills or intellectual deficits, an advantage for working with Veterans with traumatic brain injuries (TBI).<sup>24</sup> MRT was originally developed for drug therapeutic communities in prisons, which are analogous to VA Mental Health Residential Rehabilitation Treatment Programs (MH RRTPs). Prior to the common adaptation of the term “ego” in psychology in the 1930’s, the term “conation” was employed to describe the conscious process of decision-making and purposeful behavior. The term “moral reconnection” was chosen for this system because the underlying goal was to change conscious decision-making to higher levels of moral reasoning.

The evidence base for MRT in civilian samples. Multiple meta-analyses support the efficacy of MRT to reduce criminal recidivism.<sup>5-8,29,30</sup> For example, in a review of 65 studies, MRT was found to reduce the 12-month recidivism rate by 50%.<sup>30</sup> More recently, a meta-analysis of 33 published studies of MRT found that (a) the rate of recidivism among MRT participants is reduced by one-third compared to those who do not receive MRT; (b) the treatment effect size is greater in randomized trials; (c) MRT is associated with significant reductions in recidivism in community settings,<sup>25-28,30,31</sup> and (d) MRT is effective with a range of offender types.<sup>31,32</sup> Further, the Palo Alto VA’s HSR&D Center for Innovation to Implementation (Ci2i) conducted a review of the evidence base for MRT in civilian samples.<sup>23</sup> Using the Maryland Scale of Scientific Methods,<sup>33</sup> six studies were identified as being rigorous enough to provide interpretable evidence about the impact of MRT (Level 3 or higher<sup>34</sup>). All six studies demonstrated a significant reduction in reoffending in the MRT group.<sup>25,26,35-38</sup> Importantly, in community-based studies,<sup>25-28</sup> MRT was delivered in structured therapeutic communities, which provided other intensive support services that may reduce risk for recidivism (e.g., substance abuse treatment; stress and anger management; family-support services; vocational skills training).

Adaptation and testing of MRT with Veteran samples. Despite its evidence base in civilian samples, no randomized clinical trials (RCT) of MRT have been conducted with JIVs. This is an important research gap as JIVs differ from justice-involved civilians on sociodemographics (JIVs tend to be older, more educated, and more likely to be married);<sup>2,12</sup> offense characteristics (JIVs are more likely to have committed violent offenses, particularly intimate partner violence);<sup>2,12,70</sup> mental and physical health problems (JIVs have more service-related traumas and health issues, e.g., TBI),<sup>71,77</sup> and interpersonal problems (a strong connection to military culture in Veterans can increase feelings of estrangement from social networks upon return to civilian life).<sup>78</sup> Given these differences, prior research on MRT with civilian populations may not be generalizable. Some MRT steps may, for example, need to go at a faster or slower pace, or include more focus on building trust and strengthening interpersonal relations.<sup>72</sup> In response to this, the developers of MRT, in collaboration with VJP, developed a Veteran-specific curriculum for MRT, which was adapted to address the needs of JIVs.<sup>9</sup> This version of MRT is beginning to be used in VA, but not in any systematic way because there has been no trial of its effectiveness with JIVs. Testing this version of MRT in Veterans is a top priority of VJP.

MRT: Theoretical and empirical links to health-related outcomes. Aside from criminal recidivism, MRT has theoretical and empirical links to several health-related outcomes. For example, improvements in interpersonal functioning and impulse control—key mechanisms of MRT—predict better substance use disorder (SUD) and mental health treatment outcomes,<sup>73</sup> as well as better housing<sup>74</sup> and employment outcomes.<sup>79</sup> Consistent with this, MRT studies have reported improvements in SUD,<sup>25,39</sup> mental health,<sup>28,40,41</sup> and employment outcomes,<sup>25</sup> and VJP Specialists who have piloted MRT groups with JIVs reported that Veterans who participated in

these groups were more likely to utilize VA supportive housing services. Collectively, these findings provide the theoretical and empirical basis for how MRT is linked to health-related outcomes.

The theoretical and empirical links between MRT and these health-related outcomes are important, given that (a) these health-related outcomes are risk factors for future recidivism, and (b) improvements in these outcomes have been shown to reduce recidivism. For example, according to the Risk-Need-Responsivity (RNR) model of offender rehabilitation,<sup>3</sup> SUD and employment problems are robust predictors of criminal recidivism and key domains measured by valid indices of recidivism risk.<sup>75</sup> In Veterans, more mental health problems predict risk of incarceration, above and beyond other established risk factors.<sup>15,16</sup> Finally, Fontaine's work suggests better housing outcomes as a path to successful reentry from incarceration.<sup>68,69</sup>

### 3.0 Objectives

Using the new Veteran-specific manual, the overarching objective of the current proposal is to implement and evaluate Moral Reconciliation Therapy (MRT) as an intervention to reduce risk for criminal recidivism and improve health-related outcomes among justice-involved Veterans (JIVs) in VA Mental Health Residential Rehabilitation Treatment Programs (MH RRTPs). Using an effectiveness Hybrid Type 1 design, which incorporates both an RCT and a formative evaluation to facilitate future implementation, we will address two specific aims in this proposal:

**Aim 1:** At three VA facilities (Palo Alto, Little Rock, and Bedford), randomize to MRT or usual care a total of 365 Veterans who (a) are being admitted to an MH RRTP in VA, and (b) had been arrested and charged and/or released from incarceration in the past 5 years. We hypothesize that, during the 12-month study period, those who receive MRT, relative to those who receive usual care, will:

**(1a)** have a lower overall risk for criminal recidivism, operationalized via total scores on the General Criminal Thinking (GCT) index of the Psychological Inventory of Criminal Thinking Scale (PICTS),

**(1b)** have better health-related outcomes (substance use, mental health, housing, and employment), and.

**(1c)** the effects of MRT on reduced risk for recidivism and better health-related outcomes will be mediated in part by greater likelihood of completing the MH RRTP and utilizing substance use disorder and mental health continuing care services.

**Aim 2:** Use the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) framework<sup>11</sup> to conduct a formative evaluation of MRT (i.e., qualitative interviews with providers and patients). Such information will provide guidance to our operational partners in terms of broader adoption of MRT in VA, particularly with regard to identifying:

**(2a)** barriers and facilitators to implementing MRT in MH RRTPs across VA.

**(2b)** whether and/or how to adapt MRT for diverse subpopulations of Veterans (e.g., OEF/OIF Veterans; women; racial/ethnic minorities; those with PTSD).

## 4.0 Resources and Personnel

This project will be conducted at three VA sites (Palo Alto, Little Rock, and Bedford). **Dr. Daniel Blonigen** (PI; Palo Alto VA) will oversee and direct all aspects of the study. He will prepare reports to disseminate the project findings to operational partners, organize regular meetings with project staff across sites and at the Palo Alto VA, and ensure that human subjects and data security regulations are followed. **Dr. David Smelson** (Co-PI; Bedford VA) will share responsibilities for project oversight with Dr. Blonigen. He will also oversee all project-related activities at the Bedford VA. **Dr. Christine Timko** (Co-Investigator; Palo Alto VA) will advise on project design and management and completion of study aims, as well as the interpretation, dissemination, and implementation of all project findings. **Dr. Michael Cucciare** (Co-Investigator) will serve as the site PI at the Little Rock VA and direct all project-related activities at this site, as well as advise on project design and management, and interpretation, dissemination and implementation of all project findings. **Dr. Eric Elbogen** (Co-Investigator) will advise on the project design and management, particularly the sampling plan and assessment of recidivism risk, as well as the interpretation, dissemination and implementation of all project findings. **TBD Project Coordinator** (Palo Alto VA) will help to prepare data collection protocols and materials during the project start-up period; recruit patients for both project aims; conduct baseline and follow-up assessments for Aim 1, and assist with qualitative interviews for Aim 2; check and code inventories and enter the data for both aims; and construct the project databases. Three **TBD Intervention Coordinators** (Palo Alto, Little Rock, and Bedford) will prepare for, conduct, and maintain logs on the twice-weekly MRT groups, meet with the project team at Palo Alto, and participate in the monthly treatment fidelity calls with Dr. Robinson (Project Consultant and MRT co-developer) and the other Intervention Coordinators and site PIs. Two **TBD Research Health Science Specialists** (Little Rock and Bedford) will help prepare data collection protocols and materials during the project start-up period; recruit patients for both project aims; conduct baseline and follow-up assessments for Aim 1 and assist with qualitative interviews for Aim 2; check and code inventories and enter the data for both aims; construct and manage the project databases; and meet with the project team at Little Rock. **TBD Data Analyst** (Palo Alto VA) will extract, clean, and organize health services utilization data from VA administrative databases, and create variables to test the relevant Aim 1 hypotheses. **TBD Peer Trackers** will utilize their social networks as well as utilize VistAWeb on a national level to uniquely assist the Project Manager at the Palo Alto VA with tracking difficult to reach participants at all sites who are lost to follow-up at 6- and 12-months.

## 5.0 Study Procedures

### 5.1 Study Design

This study will use an effectiveness Hybrid Type 1 design<sup>10</sup> to (Aim 1) test the effectiveness of MRT in an RCT across three VA sites (Palo Alto, Little Rock, and Bedford) and (Aim 2) gather information on MRT's implementation potential in a formative evaluation.

**Aim 1:** To test the effectiveness of MRT, 365 Veterans who (a) are entering an MH RRTP, and (b) had been arrested and charged and/or released from incarceration in the past 5 years will be recruited for participation and randomly assigned to one of two conditions: usual care (UC) in the MH RRTP or MRT (condition specifics outlined below). At the beginning of the study before



participants are recruited, site PIs will generate a random number list using “randomizer.org” and create a randomization spreadsheet. Randomization will occur in blocks of six to prevent runs that might lead to unequal Ns if the full sample is not obtained. That is, we will use fixed block sizes of six to assure a roughly equal balance of subjects in the two conditions in case the study does not fully accrue. Following completion of the baseline assessment, the research assistant will add the participant to the randomization spreadsheet, notify the participant of his/her group assignment, and schedule the first MRT session for those randomized to that condition. Site PIs will review these procedures monthly with the research assistant to ensure fidelity to the process. To compare MRT to UC as UC actually exists in MH RRTPs, the number and length of project-related treatment sessions will not be equated between conditions. To reduce contamination, patients in the UC condition will not be allowed to attend MRT sessions, and the MRT group leader will remind the members at the end of each session not to discuss the group content outside of the session. Patients randomized to the UC condition will be asked not to seek out MRT during the study period of 1 year.

UC condition. All patients, regardless of condition, will receive usual MH RRTP care at the Palo Alto, Little Rock, and Bedford VAs. At each site, we will recruit from residential treatment programs that serve veterans dealing with homelessness, substance abuse, and/or mental health issues. These MH RRTPs aim to improve Veterans’ health and facilitate community reintegration by providing care (24 hours per day, 7 days per week) using a structured residential environment. The participants’ health care providers at the MH RRTPs (not the study team) will be providing usual care. No standard treatment will be withheld.

MRT condition. Patients assigned to the MRT condition will receive usual care in the MH RRTP plus two hours of MRT weekly, which will begin within a week of entering the MH RRTP in order to complete all sessions during the 3-month program stay. Over the course of 12 weeks, they will attend 24 group sessions (one-hour sessions, twice per week). The overall length of the intervention (12 weeks) corresponds to the national average of bed days of care for Veterans in MH RRTPs (3 months). In FY13, an average of 70% of patients entering the MH RRTPs at the Palo Alto, Little Rock, and Bedford VAs stayed at least 90 days (approximately 13 weeks). Thus, the majority of patients will have full exposure to the 12-week intervention by virtue of staying in the MH RRTP. For the patients who do not stay for 12 weeks, continuing care services are still available at the MH RRTP at each site, and those who have not yet completed the full MRT protocol when they discharge from the MH RRTP will still be able to get full exposure to the intervention as outpatients, and will be encouraged to do so.

The MRT curriculum consists of short assignments, grounded in cognitive-behavioral techniques, which move participants through 12 steps that aim to restructure antisocial cognitions and behaviors. To progress through the steps, patients complete homework between group meetings and at the next group each patient presents his/her homework to the group members for feedback. Participants move through steps at a rate of approximately 1-2 sessions and group sessions can incorporate new members at any time. With open enrollment, patients are presenting on different steps, which is advantageous because those who have progressed farther are able to share their insights to newer patients who are at lower steps. Open

enrollment is also advantageous as it allows for recruitment of all eligible patients as they enter the MH RRTPs.

The MRT groups will be facilitated by a combination of (a) members of the research team who are already listed in this application, (b) to-be-named (TBN) VJP Specialists from the local facility who are not MH RRTP staff, and (c) TBN staff members of the MH RRTP at each site. To reduce risk of contamination, the TBN staff members from the MH RRTPs will be specifically instructed to not provide the study intervention to any Veterans who were assigned to the usual care condition.

A full dose of MRT is 24 sessions over 12 weeks. To facilitate patients' completion of the full dose, we will (a) remind patients at the end of each MRT session about the treatment schedule and emphasize the importance of full participation;<sup>86</sup> (b) contact patients who miss a session to determine the reasons for the absence and encourage participation in future sessions; (c) offer incentives (e.g., certificates) to patients who complete the full dose<sup>87,88</sup> – such incentives are highly valued by Veterans as it allows them to demonstrate to court-related decision makers that they complied with treatment; (d) encourage participation in MRT groups as outpatients for those who have not yet completed the full dose when they discharge from the MH RRTP. These efforts notwithstanding, there is evidence that smaller doses of MRT can be effective (i.e., completion of seven steps in the MRT curriculum can lead to long-term positive changes).<sup>27,47</sup> According to Dr. Robinson and VJP Specialists who have run MRT groups, a minimum dose for this study is 12 sessions. To maximize clinical usefulness of the data, we will also examine outcomes as a function of dose.

**Aim 2:** The RE-AIM Planning Tool<sup>65</sup> will be used to conduct semi-structured interviews with MH RRTP providers and patients at each site. The RE-AIM framework<sup>11</sup> highlights five domains to evaluate an intervention's potential for implementation and widespread impact: (1) Reach (how to reach the target population with the intervention); (2) Effectiveness (how to know the intervention is effective); (3) Adoption (organizational support); (4) Implementation (fidelity of intervention's delivery); and (5) Maintenance (sustainability). The RE-AIM Planning Tool asks questions of providers and patients within each of these domains regarding key issues that should be considered when planning to implement an intervention.

Staff from each of the site's Domiciliaries will also be asked to complete the Context Scales of the Organizational Readiness to Change Assessment (ORCA), 23 items in total. This assessment will help in understanding the context of care in regard to the MRT intervention that was implemented into the Domiciliaries.

With assistance from Dr. Hagedorn (Project Consultant), Drs. Blonigen and Timko will prepare a draft interview guide for the formative evaluation, finalize it with feedback from the project team, and pre-test the interview with two MH RRTP staff members at the Palo Alto VA. We will interview six staff members at each site (the director, a nurse, a social worker, and a clinical psychologist or psychiatrist from the MH RRTP; a local VJP Specialist; and the local Mental Health Treatment Coordinator). A total of 18 VA staff members will be recruited for participation.

We will also conduct interviews with 12 JIVs from each site who agreed to participate in the study and were randomized to the MRT condition: (a) one-half will be drawn from those who completed the full dose (24 sessions) and the other half from those who dropped out and completed less than the recommended minimal dose (12 sessions).

**Sample sociodemographics.** Based on the sociodemographics of JIVs from the project team members' past studies of Veterans from VA MH RRTPs,<sup>43</sup> we expect the sample for our proposed study to be predominantly male (97%), 48 years old, on average, and 46%, 24%, and 14% will be Caucasian, African-American, and Hispanic, respectively. These estimates are highly comparable to the sociodemographics of Veterans in state and federal prisons that have been reported in national surveys,<sup>2,12,14</sup> which suggests that the typical JIV seen in VA MH RRTPs is representative of the larger population of JIVs in the US.

Some JIVs are economically and educationally disadvantaged and homeless. However, the number of such participants in our study is variable and would depend on the criteria for defining someone as disadvantaged. Due to our decision to include individuals with varied criminal justice involvement, it is important that we include a representative sample of JIVs entering a MH RRTP and, therefore, we must include such veterans in this study. If such individuals are not included in this study, we risk collecting ungeneralizable data, which (if used in clinical practice) could do harm to the patient population that was excluded from the study.

**Potential risks.** It is possible that a few of the questions asked of patients (e.g., those inquiring about stressful life circumstances; alcohol and drug use; mental health symptoms; criminal history) may cause some psychological discomfort. However, such questions are not likely to be any more distressing than the questions that are typically asked of Veteran patients in MH RRTPs. The questions asked of VA staff will be limited to their perceptions of the implementation potential of MRT within MH RRTPs, possible adaptations for different subpopulations of Veterans, barriers associated with delivery of MRT during the RCT, and what modifications to MRT could be made to maximize effectiveness. These questions are not anticipated to cause any distress or harm. Therefore, the proposed project qualifies as a "minimal risk" research study according to 45 CFR 46.117(2)(c). Nonetheless, precautions will be taken to further minimize participants' risks in the study. Specifically, during the informed consent process, participants will be told about the nature of our research study, the types of questions that will be asked of them, and the potential risks associated with these procedures. All participants will be given an opportunity to have any questions answered to their satisfaction prior to being asked to provide informed consent.

**Potential benefits.** This research involves the risk of minor discomfort on the part of some participants. This risk, however, is more than offset by the potential benefits to the JIVs who participate in the study, which are (a) reducing risk for criminal recidivism, (b) improving health-related outcomes (substance use, mental health, housing, and employment), and (c) increasing the likelihood of completing the MH RRTP and utilizing SUD/mental health continuing care services. We have conducted previous prospective studies with Veteran mental health patients in residential programs using these types of research procedures. In this prior work, no untoward events have occurred and no breaches of confidentiality have taken place.

**Project timeline.** The proposed study will take 4 years to complete. The first 3 months will be used for the RCT's start-up (e.g., staff MRT trainings; preparation of data collection protocols). Recruitment for the RCT will begin in Month 4 and during the next 24 months, 365 patients will be enrolled and complete baseline interviews. Follow-up assessments will begin 6 months after the first baseline assessment (Month 10) and end in Month 40. For the formative evaluation, we will recruit, conduct, transcribe, and code qualitative interviews with (a) patients from Months 18 to 30, and (b) staff from Months 30 to 36. Analyses of Aim 1 and 2 data, report writing, and dissemination of the primary findings of both aims to our operational partners will occur in Months 40-48.

## **5.2 Recruitment Methods**

**Aim 1:** We will recruit participants through MH RRTPs at each site. Veterans entering these programs will be screened by MH RRTP staff in consecutive order during the admissions process to determine study eligibility. Specifically, during the admissions process into the MH RRTP, a staff member will ask the Veteran if they were arrested and charged with a criminal offense and/or released from incarceration in the past 5 years. This is a standard question of all Veterans who enter MH RRTPs at each site. In addition, the MH RRTP staff member will verify that the Veteran is not pregnant and is conversant in English. MH RRTP staff will then ask eligible patients for permission to be contacted about the study by project staff (i.e., the MH RRTP staff member will hand the Veteran the Recruitment Sheet) and will provide study personnel with a list of these patients and their contact information (i.e., their phone number) three times per week. If the number of patients referred to the study exceeds recruitment goals, we will randomly select as many patients as needed. At each site, we will keep a list of all eligible patients whom we contacted to solicit participation in the study. Prior to contacting a potential patient, we will first verify that that patient was not already approached about participating in the study during a previous admission.

We plan to enroll approximately five patients per month at each site (approximately 1-2 patients per week). This approach aligns with standard delivery of MRT, which consists of open groups with rolling enrollment. The proposed pace will maintain appropriate group size for the MRT group facilitator and allow the research assistants to conduct assessments. 365 patients will be enrolled and complete baseline interviews. The sample will be stratified by site such that 122 patients (with rounding) will be recruited separately from Palo Alto, Little Rock, and Bedford, with 61 patients entering into each condition at each site. Regardless of group assignment, participants will also be asked to complete an in-person baseline assessment and two follow-up assessments (in-person or via phone) 6 and 12 months later. Participants will be reimbursed \$25 for the baseline interview, and \$50 after completion of each follow-up interview. Participants will have the option of being reimbursed with gift cards immediately after the completion of each interview, or receiving a check via mail in 6-8 weeks.

**Aim 2 (Qualitative Interviews):** We will interview six staff members at each site (the director, a nurse, a social worker, and a clinical psychologist or psychiatrist from the MH RRTP; a local VJP Specialist; and the local Mental Health Treatment Coordinator). We will also conduct interviews with 12 JIVs from each site who agreed to participate in the study and were

randomized to the MRT condition: (a) one-half will be drawn from those who completed the full dose (24 sessions) and the other half from those who dropped out and completed less than the recommended minimal dose (12 sessions). Although individuals cannot represent entire groups, we will include a diverse sample of Veterans based on age, gender, race/ethnicity, era of military service, and diagnoses (e.g., PTSD). Interviews will last 30-60 minutes; be conducted in person or via phone by Drs. Blonigen and Timko, as well as the research assistants at each site; and audiotaped with consent. Staff interviews will take place after all patient participants have completed the intervention phase of the RCT. Specifically, within two weeks of the last MRT session for patient participants at a given site, a research staff member at the site will attend MH RRTP staff meetings and distribute the information sheet that is included in this Central IRB application. MH RRTP staff will then be informed that if they are interested in participating, they can contact the number listed at the bottom of the information sheet. Patient interviews will take place after participants have either completed or dropped out of the intervention. Specifically, within 2 weeks of completing their last MRT session, patients will be re-contacted via phone and invited to participate in the 30-60 minute interview.

### **5.3 Informed Consent Procedures**

**Aim 1:** Consent will be obtained by the site Project Coordinator, Intervention Coordinator, and/or Research Health Science Specialist who is knowledgeable about the study and trained to review the consent form with potential participants. Informed consent will be obtained in-person at one of the three VA sites (Palo Alto, Little Rock, and Bedford) prior to the start of the baseline assessment. At that time, the study will be explained in-depth and the research team member will go over all elements of the consent form with the patient. All patients will be given an opportunity to have any questions answered to their satisfaction prior to being asked to provide informed consent. Patients will be informed that they will be assigned either to “usual care” or two additional group sessions per week in the MH RRTP. The research team member will ask the potential participant questions to ensure that they understand the procedures and risks. The Research Assistants for this project (those listed in the personnel section) will be trained in Human Subjects protections and will have formally delegated responsibilities to obtain informed consent.

Prior to entry into the study, patients will be told explicitly that should study personnel learn at any time that the patient poses a danger to self or others, the researchers will need to break confidentiality, which includes making a report to the proper authorities and/or providing additional help to the patient as dictated by VA regulations and state law. Providing patients with this information is a standard and integral part of the informed consent process for research studies with Veterans and has not deterred mental health patients from participating in our studies. Further, we will use methods developed in previous and ongoing RCTs and other studies of the project team members to ensure valid and informed consent – i.e., extensive training and monitoring of project staff obtaining consent; organizing the content of the consent form into separate modules; questioning prospective participants to determine the extent of their understanding of the study purpose, procedures, and risks; encouraging the patient to ask questions regarding anything not understood.

**Aim 2:** Veterans admitted to the MH RRTPs at the project sites who agreed to participate in the study and were randomized to the MRT condition, and either (a) completed a full dose of MRT (24 sessions), or (b) dropped out and completed less than the recommended minimal dose (12 sessions), will be recruited to participate in the formative evaluation. VA staff members at each site (the director, a nurse, a social worker, and clinical psychologist or psychiatrist from the MH RRTP; a local VJP Specialist; and the local Mental Health Treatment Coordinator) will also be recruited for participation in the formative evaluation. The Veteran patients will be contacted by a member of the project team who will arrange to meet with the prospective participant to explain this portion of the project (see “Phone Script for Veterans”). Written informed consent to participate in this part of the project will already have been obtained from the Veteran patients during the informed consent procedures for Aim 1.

Verbal, rather than written, informed consent will be obtained from VA staff for Aim 2 (see Information Sheet – Waiver of Documentation of Informed Consent). Specifically, a research staff member at each site will attend MH RRTP staff meetings and distribute the aforementioned Information Sheet. MH RRTP staff will then be informed that if they are interested in participating, they can contact the number listed at the bottom of the Information Sheet. VA staff members who contact a research staff member expressing interest in participating will then be read the phone script for VA providers.

#### **5.4 Inclusion/Exclusion Criteria**

Veterans who (a) are entering a mental health residential rehabilitation treatment program (MH RRTP) at one of three study sites (Palo Alto, Little Rock, or Bedford VA), and (b) had been arrested and charged and/or released from incarceration in the past 5 years prior to MH RRTP admission will be eligible for participation.

The only exclusion criterion is being too cognitively impaired to understand the informed consent process and other study procedures. Patients will be screened for cognitive impairment using the Montreal Cognitive Assessment’s section on Orientation. For patients who are not able to correctly answer the Orientation (date, location) items, the research assistant will further educate the patient on the purpose of the study and procedures until he or she is able to recall and reflect on these procedures. Patients who are unable to do so will be deemed too cognitively impaired to understand the study’s procedures, participate meaningfully in MRT, and respond to interviews, and therefore will be ineligible (in our past studies of Veterans from MH RRTPs, only 1% of prospective participants was excluded on this basis). For those who are eligible, written informed consent will be obtained, and the baseline assessment will be administered.

#### **5.5 Study Evaluations**

**Baseline assessment.** Research assistants will collect baseline self-report data on sociodemographics (e.g., age, gender, race/ethnicity, marital status, education, and income) and (a) recidivism risk and criminal history; (b) health-related functioning; (c) SUD/mental health treatment and mutual-help history; and (d) mechanisms of MRT. This assessment will be conducted in person at the MH RRTP and will take 60 minutes to complete. We will pre-test the assessment protocol to ensure that it can be completed within this timeframe.

Recidivism risk and criminal history. Recidivism risk will be measured with the Psychological Inventory of Criminal Thinking Styles (PICTS),<sup>75</sup> which consists of 56 items to assess antisocial cognitions and attitudes. These items are summed to create a General Criminal Thinking (GCT) score, which provides an overall index of recidivism risk. Scores on PICTS scores have good internal consistency,<sup>80,81</sup> and, in the prediction of general recidivism (e.g., rearrests), multiple meta-analyses indicate that the validity of the PICTS GCT score is high and provides incremental prediction of this outcome above and beyond state risk factors such as age and criminal history, as well as interview-based measures of recidivism risk (e.g., Level of Service Inventory).<sup>75,83</sup>

Data on patients' criminal history, including type and recency of criminal justice involvement, will be obtained from a modified version of the legal section from the Addiction Severity Index (ASI)<sup>48</sup> (i.e., age of first arrest and charge; number of times arrested and charged, number of times incarcerated, and total number of months incarcerated in past 12 months, past 5 years, and lifetime; number of months since most recent criminal justice event; and most recent offense for which the Veteran was arrested, charged, or incarcerated). We will verify the ASI legal section data using the HOMES assessments, which include information on criminal history and are administered to all patients entering VA MH RRTPs, and all patients served by VJP. Based on the empirical literature, patient reports of their criminal history are highly correlated with their criminal records.<sup>85</sup>

Health-related functioning. We will use the ASI to assess substance use, and mental health, housing, and employment status at baseline. In addition to items on housing, the ASI assesses functioning in several problems areas, e.g., alcohol use, drug use, psychiatric, and employment. In each domain, items measure the number, extent, and duration of problems (lifetime and past 30 days). Composite scores are produced from sets of items that are standardized and summed (range from 0 to 1; higher scores indicate poorer outcomes), which provide internally-consistent indices of patient status in the relevant domains in the past 30 days. Prior work supports the validity of self-reports on these areas.<sup>50</sup> To further assess substance use, the Time-Line Follow Back (TLFB) will be administered. The TLFB is a retrospective, calendar-based measure of substance use, which has been validated for administration in-person or via phone<sup>57</sup> and will provide information on quantity and frequency of substance use in the 6 months prior to the baseline assessment (i.e., percent days of use; percent days abstinent; most consecutive days using; most consecutive days abstinent). To further assess psychiatric status, the PHQ-9 will be administered to assess symptoms of major depression, and the PTSD Checklist (DSM-V version) will be used to assess symptoms of PTSD. VA records will be used to gather SUD and mental health diagnoses on patients at the time of admission to the MH RRTP, per ICD-9 codes linked to the appropriate bedsection code in the inpatient files.

SUD/mental health treatment and mutual-help history. We will use the ASI to assess participants' treatment history (i.e., any care [yes/no]; number of visits over the lifetime and past 12 months) for SUD (outpatient, residential, pharmacotherapy) and mental health (outpatient, inpatient, residential). Information on VA health services utilization in the past 12 months will be collected via patient records for these domains of care. Data on non-VA health care utilization will be collected to help determine whether the two condition arms are balanced and ensure that any changes in utilization of VA services are not due to changes in non-VA care. To measure attendance (yes/no; number of meetings) and involvement in mutual-help groups (lifetime, past 12 months) we will use items from the Alcoholics Anonymous Inventory.<sup>49</sup>

Mechanisms of MRT. Interpersonal functioning will be assessed with the ASI family/social functioning composite, and a 32-item version of the self-report Inventory of Interpersonal Problems,<sup>54</sup> which has good reliability and validity with mental health and criminal justice populations.<sup>55</sup> Close affiliations with friends who (a) engage in criminal activity and (b) abuse drugs and alcohol will be assessed, respectively, with the Measures of Criminal Attitudes and Associates (MCAA) and select items from the Life Stressors and Social Resources Inventory (LISRES).

**Follow-up assessments.** Research assistants, blinded to patients' condition assignment, will collect self-report data from patients at 6 and 12 months. We will use an intent-to-treat design and follow all patients who are randomized to the MRT condition. To maximize retention, follow-up data will be collected via either phone or in-person interviews. Each follow-up interview will last 60 minutes, with the option of two shorter sessions if needed due to fatigue or scheduling issues. We will pre-test the assessment protocols to ensure that they can be completed within this timeframe. For the Bedford site, upon completion of the 12-month follow-up visit, research staff will enter a close-out note in the participant's VA health record. This note will confirm that the patient's active participation in the study has ended. However, extraction of participants' medical record data will continue beyond this point, as detailed in the HIPAA authorization form.

Recidivism risk and recidivism. The PICTS is sensitive to change and will be readministered to assess overall risk for recidivism at the follow-ups. The ASI will also be readministered to measure criminal recidivism since the prior assessment (i.e., any arrest, incarceration, or violation of parole or probation; number of self-reported criminal acts regardless of whether an act was detected). ASI interviews can be conducted reliably and validly in-person or via phone.<sup>56</sup>

Health-related functioning. The ASI will assess recent (past 30 days) functioning on the health-related outcomes using the sociodemographic information and composite scores. The Time-Line Follow Back (TLFB), a retrospective, calendar-based measure of substance use, will be re-administered at each follow-up assessment.

MH RRTP completion and SUD/mental health continuing care utilization. MH RRTP completion will be determined from VA administrative databases. Data on SUD/mental health continuing care utilization since the prior assessment will be obtained from (a) VA administrative databases, for VA care; (b) an interview on non-VA health care utilization, for non-VA care; and (c) the Alcoholics Anonymous Inventory for mutual-help group attendance. From these data sources, we will calculate whether SUD/mental health care was received (yes/no) and the amount of care received (number of outpatient visits; number of mutual-help group meetings). To be comprehensive, we will also assess whether SUD or mental health inpatient/residential care occurred since the prior assessment (i.e., any care [yes/no], number of bed days of care).

MRT mechanisms. We will re-administer the measures used at baseline to assess interpersonal functioning and affiliations with antisocial and substance abusing peers.

Measuring utilization of VA health care services. We will collect data on patients' use of VA health care (SUD; mental health) to test our hypothesis (i.e., effects of MRT will be mediated in part by service utilization). National data extracts from the Patient Treatment Files (PTF) and National Patient Care Databases (NPCD) will be used to determine utilization of VA residential (MH RRTP) and outpatient care. Corresponding information on utilization of VA-paid care at non-VA facilities is available in the national Fee Basis files and will be searched for all study participants. These datasets are maintained at VA's Corporate Data Warehouse and available, in SAS format by fiscal year, through



VA's VINCI intranet site. We will obtain all PTF, NPCD, and Fee Basis files for study participants for all health care encounters that occur in a 12-month period prior to, and ending 12 months after, study enrollment. From the PTF files of residential care, we will extract the following data: patient ID (i.e., SCRSSN); station; treating specialty (bedsection); date of service; diagnostic and procedure codes; and length of stay. From the NPCD files of outpatient care, we will extract the following data: patient ID; station; clinic stop code; date of service; and diagnostic and procedure codes. Care identified in the Fee Basis files will be classified by setting and purpose of visit using several variables. Specifically, at each assessment we will ask patients to report on non-VA care, including type, timing, and duration of care.

**Arrest and incarceration records.** We will obtain state and federal arrest and incarceration records. We anticipate that participants will be difficult to reach by phone or through alternate contacts and may have no current information in their VA medical health record. This information is essential to determining if there is a difference between usual care and the MRT group, whether those in the treatment condition have a lower overall recidivism risk

**Fidelity assessments.** To assess ongoing fidelity to the MRT condition, group sessions will be video- and audio-taped (with consent) and evaluated against a Fidelity Checklist by Dr. Blonigen and the other site PIs using the following schedule: (1) the first eight sessions for each IC, which corresponds to the first month of running MRT groups, will be assessed for protocol fidelity and the IC will be provided with corrective feedback; (2) one session for each IC will be reviewed at random each month by the site PI to ensure fidelity to the intervention. Dr. Robinson will also lead monthly treatment fidelity calls with the site PIs and ICs to (a) maintain adherence to the MRT protocol across sites, and (b) review the results of the de-identified MRT Fidelity Checklists that were completed by site PIs. For ICs who fall below an 80% rating on the checklist, a one-on-one, hour-long consultation with Dr. Robinson will be triggered to provide corrective feedback to the IC. Dr. Robinson has a protocol for fidelity drift, which he has used to retrain ICs in his past MRT studies. A follow-up, hour-long consultation with Dr. Robinson will take place two weeks later to review the IC's progress.

## 5.6 Data Analysis

**Sampling plan: Power analysis.** To ensure sufficient variability in our outcomes, and in turn increase the power to test study hypotheses, we focused our Specific Aims on overall risk for recidivism (i.e., PICTS GCT total scores) and functioning on health-related risk factors, rather than recidivism per se (e.g., rearrest), as the latter may have a low base rate within the 12-month study period. Based on meta-analyses<sup>7,8</sup> and studies of MRT mechanisms,<sup>73</sup> we expect a medium effect size (Cohen's  $f^2=.15$ )<sup>67</sup> in multiple regression models testing condition (UC vs. MRT) as a predictor of recidivism risk and the health-related outcomes. However, given the planned moderation analyses, we calculated the power to detect small effect sizes (i.e.,  $f^2=.02$ ). To account for having patients at three sites, power analyses using G\*Power<sup>82</sup> were based on having six cells (two conditions per site). A sample size of 292 (146 in each condition) will provide 80% power to detect a small effect size at an alpha of .05 (two-tailed test). To account for the moderators, we calculated the available power and effect size that could be detected in a regression model, given (a) our projected sample size, and (b) the addition of six more predictors in the model (i.e., the three moderator variables listed above and three interaction terms between these moderators and the variable of condition). Based on an N of 292 and alpha of .05, we would have 80% power to detect an  $f^2$  of .07, a small-to-

medium size effect.<sup>67</sup> We are predicting 20% attrition at the follow-ups. This was the rate of attrition in prior longitudinal studies of project team members of Veteran treatment samples with high rates of criminal histories.<sup>44-46</sup> Thus, we will recruit a total of 365 patients (183 in each condition, with rounding). If attrition reaches 30%, we will still have 80% power to detect an  $f^2$  of .08.

**Procedures to locate and follow patients.** To ensure high follow-up rates (>80%), we will adhere to well established procedures used by members of the project team for locating and following mental health patients in longitudinal studies who are homeless and have extensive criminal histories. Specifically, a form will be included in the baseline assessment to obtain information on patients' mailing address, home/work/cell phone numbers, and employment information; contact information from a parole/probation officer, or case manager; and up to three additional individuals to be used in the event that contact with the participant is lost. This information will be collected and updated at all assessments. To complete follow-ups, project staff will persist in their efforts (for a minimum of three documented attempts) to locate a participant for the duration of the data collection period. These efforts will include mailing reminder cards to participants two weeks in advance of their scheduled follow-up interview. The card will include an 800 telephone number for participants to call. Although some participants will be homeless, in our past studies, homeless participants often contacted us for follow-ups or were successfully contacted by project staff when returning for VA appointments. We also have connections with local homeless shelters and providers from VJP and VA supportive housing programs, which will greatly aid our ability to track participants. A participant will be considered "not located" only if s/he is not contacted at the time of the data lock. Once located, repeated attempts (a minimum of three) will be made to contact participants by phone and/or mail.

We are confident we will be able to achieve an 80% response rate, given that we have achieved follow-up rates above 80% in prior longitudinal studies (e.g., 92% at a 1-year follow-up<sup>45</sup>; 84% at a 2-year follow-up<sup>46</sup>) using the same rigorous tracking procedures as proposed here with populations that had high rates of justice involvement and homelessness at intake. Further, in our current HSR&D study of Telephone Monitoring with dually-diagnosed psychiatric inpatients, 98% of participants have access to a phone for research assessments. To maximize retention, we will collect follow-up data via either telephone or in-person interviews, which will include visits to jails or prisons to interview participants who are incarcerated. We will use "peer trackers" to assist with locating clients, as they have social networks to track down participants and have been highly effective in our past studies. "Peer trackers" will also utilize the program, VistAWeb, on a national level to locate difficult to reach participants for the follow-up assessments.

**Aim 1: Analytic plan.** The project data will be analyzed at the Palo Alto VA by Drs. Blonigen and Timko. We hypothesize that those in the MRT (vs. the UC) condition will (1) have lower overall risk for criminal recidivism, and (2) better health-related outcomes (i.e., substance use, mental health, housing, and employment); and (3) the effects of MRT on reduced risk for recidivism and better health-related outcomes will be mediated in part by greater likelihood of completing the MH RRTP and utilizing SUD/mental health continuing care services. To test these hypotheses, we will do the following:

Examine distributions. Generalized mixed-effects regression models (GLMM) will be conducted. However, prior to conducting these models, we will examine the distribution of the outcome and

predictor variables. If non-normality in variable distributions is observed for the baseline comparisons between the UC and MRT conditions, we will use data transformation or nonparametric tests of equality between groups. One of the benefits of GLMM is its capacity to accommodate different conditional distributions for each outcome variable by choosing appropriate link and variance functions within GLMM.

Examine baseline equivalence. We will use independent group t-tests and chi-square tests for continuous and categorical variables, respectively, to determine whether patients assigned to the UC and MRT conditions are comparable at baseline on (a) age, race/ethnicity, marital status, education, and income; (b) PICTS GCT scores; (b) substance use, mental health, housing, and employment status; (c) SUD/mental health treatment utilization and mutual-help group participation; and (d) percent incarcerated in the past 5 years, number of months since the most recent criminal justice event (i.e., charged or released from incarceration), and extent of criminal history (i.e., scores on a composite of number of charges, number of times incarcerated, and total number of months incarcerated). We do not anticipate baseline differences; however, if they are detected, the variables on which groups differ will be controlled in the regression analyses.

Compare the UC and MRT conditions on study outcomes. We will use GLMM regressions to compare the UC and MRT conditions on overall risk for recidivism (PICTS GCT scores); and substance use (ASI alcohol and drug composites; TLFB scores), mental health (ASI psychiatric composite; PHQ-9 and PCL-5 scores), housing (ASI–number of months in a stable residence), and employment status (ASI employment composite) over the study period. GLMM models permit modeling of repeated-measures data; do not require that all participants be measured at all time points to be included in analyses; and apply to continuous, dichotomous (e.g., MH RRTP completion), and Poisson-distributed outcomes (e.g., number of SUD/mental health outpatient visits).<sup>58</sup>

In the regression model, we will take into account that the repeated measures over the three time points are clustered within each individual by treating time as a single repeated factor. The main factor of interest is condition (UC, MRT). For each dependent variable, a linear trajectory for each patient will be estimated. The intercept is the estimate of the patient's score at baseline. The slope is the estimate of the linear response trajectory and the error term represents how well the linear model fits the patient's data. For each outcome, three between-person parameters will be estimated: (a) the average baseline score for each group (UC, MRT); (b) the average slopes over time for the UC and MRT groups; and (c) the interaction of condition by site. We will employ full maximum likelihood estimation, and, in combination with random effects, we will examine further constraints on covariance structure (e.g., auto-regressive) and choose that which yields the best fit by standard goodness-of-fit indices (e.g., Akaike's Information Criterion).

As part of the model building process, we will examine the error distributions to assess whether random effects meet the assumptions of normality and homoscedasticity and adjust the models as needed. We will specify the appropriate distribution of the outcome variable in the regression model (normal, binomial, Poisson) and choose the appropriate link and variance functions.

Because the MRT intervention will be standardized and monitored for fidelity, we do not expect variations in outcomes associated with ICs across sites. However, to examine this possibility we will specify a model where random effects of patients are nested within random effects of the ICs. If the fit of the model is similar to one without nesting, we will not continue to control for it.<sup>59</sup>

Examine moderators. For the direct effects of condition (UC, MRT) on study outcomes (overall risk for recidivism; and substance use, mental health, housing, and employment status), we will test three moderators of these effects: (a) incarcerated or not in the past 12 months; (b) number of months since the most recent criminal justice event (i.e., charged or released from incarceration); (c) an index of extent of criminal history (i.e., a z-scored composite of number of charges, number of times incarcerated, and total number of months incarcerated in lifetime). The continuous moderators (number of months since the most recent criminal justice event, and index of criminal history) will be zero-centered. The main effects of these moderator variables and the interaction terms between condition (UC, MRT) and each moderator will be entered into the same regression models described above. If any interaction terms are significant, conditional moderators will be evaluated to assess the direction and magnitude of effects within subgroups (e.g., re-entry subgroup).<sup>66</sup>

Examine mechanisms (i.e., reasons MRT is effective). MH RRTP completion (yes/no) and SUD/mental health continuing care utilization (outpatient attendance [yes/no] and amount; mutual-help group attendance [yes/no], number of meetings) will be examined as mediators between condition and risk for recidivism, and between condition and the health-related outcomes at the 6- and 12-month follow-ups.<sup>60,61</sup> We will conduct regression models that correspond to a hypothesized causal sequence among (1) MRT, (2) one of our hypothesized mediators, and (3) better outcomes. In each model, we will control for relevant covariates (e.g., baseline values for sociodemographics and the dependent variable). In the first regression, a dummy variable representing the MRT intervention will be the independent variable and the dependent variable will be the outcome (e.g., PICTS GCT scores). In the second regression, MRT will be the independent variable and the dependent variable will be the potential mediator. In the third regression, the potential mediator will be the independent variable and the dependent variable will be the outcome. If the coefficient for MRT or a potential mediator is significant in all of these cases, we will proceed. In the final regression, the MRT dummy variable will be entered simultaneously with the potential mediator as predictors of the outcome. If the coefficient for the potential mediator is significant and the coefficient for the MRT dummy variable on the outcome is reduced, we will conclude that mediation is supported and will evaluate whether the indirect effect is significant.<sup>62</sup> To account for variability in intensity of continuing care services, we will test for significant interactions on outcomes between our measures of continuing care and a variable for site.

We will also determine if any significant, direct effects of MRT on (a) overall risk for recidivism, and (b) the health-related outcomes, are mediated by specific mechanisms of MRT (i.e., improvements in interpersonal functioning and reductions in affiliations with antisocial and substance abusing peers). We will conduct GLMM regression models that correspond to a hypothesized causal sequence among (1) MRT (vs. UC), (2) the potential mechanisms, and (3) one of the outcomes, and control for covariates. Finally, we will conduct regression analyses

(controlling for relevant covariates) to examine associations of MRT dose (number of group sessions attended; number of steps completed) with patient outcomes at the follow-ups. Based on prior work<sup>27,47</sup> and the recommendations of VJP Specialists who have previously conducted MRT groups with Veterans, we will explore whether completion of 12 sessions is as effective as a full dose (24 sessions).

Adjust for contamination and missing data. To address the possibility of contamination, if we learn that MRT-related information was shared with UC participants, the records of those UC participants will be flagged, and contamination-adjusted intention-to-treat analyses will be calculated<sup>84</sup> (i.e., the effect of treatment assignment on outcomes is adjusted by the percentage of participants assigned to the UC condition who may have received the treatment). To minimize missing data, we will train research assistants on the importance of completing each item while respecting the rights of patients to refuse answers. Based on our prior studies, we expect to achieve less than 5% missing data on each variable at each assessment, over and above any attrition. We will obtain as high a follow-up rate as possible at each assessment. In contrast to MH RRTP completion and SUD/mental health continuing care utilization, which will be collected primarily via VA administrative data at the 6- and 12-month follow-ups, data on recidivism risk and health-related outcomes at the follow-ups will be collected via patient reports, and will therefore have more missing data due to expected attrition at those time points. GLMM's strengths are the ability to use all available data, including data on respondents who may not have provided data at each assessment. All patients who enter the study will be included in GLMM analyses. However, we will also conduct analyses that include only patients who attended at least the first MRT session. We will use a model-based multiple imputation procedure and will impute missing values using least-squares regression imputation.<sup>63</sup> We will select a set of measures that are associated with the variable at issue and use it in a series of iterated least-squares regression models to generate a predicted value for the variable being imputed, and then substitute the missing value with the predicted value.<sup>64</sup>

**Aim 2: Analytic plan.** De-identified audio-files of the staff and patient interviews will be transcribed. The transcription will be performed by a professional medical transcription agency specifically chosen for this study. Drs. Blonigen and Timko will review the transcripts of these interviews, and take detailed notes using the structure of the RE-AIM Planning Tool. With feedback from project team members, we will create tables to summarize and categorize the barriers/facilitators of MRT implementation at the system, provider, and patient levels, and include potential solutions and potential-to-leverage columns that contain evidence-based implementation tools to be considered for more widespread usage of MRT. These analyses will reduce and display the data. In conjunction with the tables, we will identify a small set of themes within each domain of the RE-AIM framework that signify triangulated findings (e.g., factors that would facilitate and maintain a program's use of MRT in a way that fits within the clinical and administrative infrastructure of the facility). The purpose will be to capture in-depth information on patient, provider, and contextual factors that will facilitate or hinder the successful implementation of MRT. Such factors will be used to inform post-hoc interpretation of project findings and guide development of action plans to be tested in subsequent implementation projects. If Aim 1 hypotheses are not supported, we will use this analytic approach to identify barriers associated with delivery of MRT during the RCT, and what modifications to MRT could

be made to maximize effectiveness. Such information will be shared with our operational partners to guide their future efforts to reduce recidivism risk among JIVs.

## **5.7 Withdrawal of Subjects**

Prospective participants will be told that they may withdraw from the study at any time and refrain from answering specific questions; that all information will be confidential and used only for the purposes of the research study; and that they may contact the PI (Dr. Blonigen) or a research assistant with any questions at any time.

## **5.8 Right of Investigator to Terminate Participation**

The investigators may also withdraw the participant from the study and the study intervention may be stopped without consent for one or more of the following reasons: 1) Failure to follow the instructions of the investigators and/or study staff, 2) Continuation in the study could be harmful to the participant, 3) The study is cancelled, 4) Other administrative reasons, and 5) Unanticipated circumstances..

Any withdrawal from the study on the part of investigators will not affect the standard care that the participant is receiving in the Domiciliary Program or any other VA health care to which the participant is entitled to.

## **6.0 Reporting**

**Protection against risk.** In attempting to contact potential participants (or even those who are already enrolled in the study) the research assistant will explain to any other person who they reach that s/he is trying to locate the individual regarding a health survey. The project will never be described to any non-participant the research assistant may reach as a study of criminal recidivism, mental health problems, substance abuse, homelessness, or unemployment, nor will we label any individual as a criminal offender, mental health patient, substance abuser, homeless, or unemployed. To further preserve confidentiality, we will not include the respondent's name on any interview. Instead, these documents will be given experimentally-assigned ID numbers. The master list that contains names, contact information, and ID numbers will be kept in password- and fire-wall protected computer files that are accessible only to project staff, and all data with personal identifiable information will be stored in locked file drawers.

The Intervention Coordinators will be thoroughly trained and closely supervised during the period in which they are conducting the MRT groups. The research assistants will also be thoroughly trained and closely supervised during the data collection period. For example, initial and maintenance training on the Addiction Severity Index (ASI) begins with viewing a four-part training DVD that is distributed by the ASI's developers. Training of the research assistants will also entail the trainee observing other staff conducting interviews, being supervised by another experienced interviewer while conducting interviews, and receiving feedback.

All contacts and interviews will be conducted in a sensitive manner that protects the dignity of respondents. Intervention Coordinators and research assistants will be prepared for situations in which a respondent expresses the need for help for a personal or emotional problem. If a respondent verbalizes such a need while they are still under the care of the MH RRTP, the research team member will ask if s/he can inform the program staff about the patient's problems. If a respondent verbalizes such a need while they are no longer a resident of the MH RRTP, the research team member will ask the participant if s/he would like a referral for counseling or treatment. If the respondent wants such information, the research team member will provide it.

In addition to the Intervention Coordinators, the research assistants will be trained and prepared for situations in which a participant expresses severe distress (e.g., serious depression with suicidal tendencies). Importantly, at the beginning of the study (i.e., during the baseline assessment and during the MRT intervention groups), the participants will be residents of the MH RRTPs at each site and will be under the close supervision of the mental health and medical staff in these programs who can directly address these situations. However, in the event the participant expresses suicidal or homicidal ideation or other serious psychiatric or medical symptoms during a time when the participant is not a resident of the MH RRTP, the PI at all three sites will be notified immediately. At the Palo Alto site, Dr. Blonigen (PI) is a licensed clinical psychologist. At the Little Rock site, Dr. Cucciare (Co-Investigator) is a licensed clinical psychologist. At the Bedford site, Dr. Smelson (PI) is a licensed clinical psychologist. These members of the project team will be available to consult with the other research team members and/or speak with the participant if any concerning events arise. At the Palo Alto VA, other licensed mental health professional staff (10 additional psychologists at the Center for Innovation to Implementation) will act as back-up contacts in the event that Dr. Blonigen and project affiliate staff are not available for consultation. At both the Little Rock and Bedford VAs, the MH RRTP Directors and up to 2 clinical providers will serve as back-up contacts in the event that the site PI and project affiliate staff are not available for consultation. All project staff will have been trained on VA's suicide risk assessment and response guidelines, including the capability of directly connecting suicidal participants to the 24-hour VA suicide hotline, as well as arranging with local mental health crisis management staff to assess and potentially hospitalize the patient. Subsequent to any participant's expression of severe distress, project staff will make all reasonable attempts to re-contact the participant to monitor his/her well-being until the acute situation is resolved.

This project does not include administration of alcohol or other drugs, and is not a human laboratory study of alcohol or other drug intake. The PIs will be made aware of all potentially negative or concerning participant contacts and will determine when events are serious adverse events or non-serious adverse events. Any serious adverse events will be reported to the appropriate IRBs within 48 hours.

## **7.0 Privacy and Confidentiality**

**Patient privacy and confidentiality.** Data from patients will be obtained by means of interviews and self-report questionnaires administered at three time points (the first of which will be conducted in person, the last two either in-person or via phone) for the RCT, and a one-time semi-structured interview (conducted in person or via phone) for the formative evaluation. For the RCT, data from the VA Corporate Data Warehouse (CDW) will also be extracted to obtain patients' substance use disorder (SUD) and mental health service utilization during the study period. The data extracted from CDW will be stored only on a secure VA VINCI project folder allocated to this study by VINCI and maintained by VINCI OI&T personnel. Data from VA staff members will be obtained from a one-time semi-structured interview administered either in-person or via phone.

All research material will be collected solely for the purposes of the study. All subject data will remain confidential after it is collected. All collected data will be stored in a format that is identifiable only by an experimentally-assigned ID number rather than with participants' name or any other personal identifiable information.

In attempting to contact potential participants, or even those who are already enrolled in the study, the research assistant will explain to any other person who they reach that s/he is trying to locate the individual regarding a health survey. The project will never be described to any non-participant the research assistant may reach as a study of criminal recidivism, mental health problems, substance abuse, homelessness, or unemployment, nor will we label any individual as a criminal offender, mental health patient, substance abuser, homeless, or unemployed. To further preserve confidentiality, we will not include the respondent's name on any interview. Instead, these documents will be given experimentally-assigned ID numbers. The master list that contains names, contact information, and ID numbers will be kept in password- and fire-wall protected computer files that are accessible only to project staff, and all data with personal identifiable information will be stored in locked file drawers.

For any follow-up interviews with incarcerated participants, these will be conducted via phone and will not be videotaped or audio-recorded. We will use similar privacy protections for incarcerated participants as we have used to ensure the privacy of participants in our past studies (e.g., inpatients in shared hospital rooms). Specifically, after asking participants a question (which others in the vicinity will not be able to hear), the interviewer will give the response options to the participant and ask the participant to only say the number or letter corresponding to their answer (e.g., "5" for "extremely"). If the participant believes s/he cannot fully answer any particular questions in this environment, then they will not have to answer those questions.

Data from providers will be obtained by means of a one-time semi-structured interview (conducted in person or via phone) for the formative evaluation. All provider participants will be informed that their decision to participate or not in the interview and their responses to the interview itself will not be disclosed to their supervisors or other VA employees or Veterans. To ensure this protection, a research staff member will attend MH RRTP staff meetings and distribute the information sheet that is included in this Central IRB application. MH RRTP staff



will then be informed that if they are interested in participating, they can contact the number listed at the bottom of the information sheet.

**Data Collection:** The self-report participant data that is collected from the baseline, 6-month follow-up, and 12-month follow-up interviews will be entered and managed using the program, IBM Statistical Package for the Social Sciences (SPSS), Version 21. This data will be entered, managed, and stored at the coordinating site (VA Palo Alto). Research Assistants at Bedford VAMC and Central Arkansas Veterans HCS will scan the completed baseline and the 6- and 12-month follow-up assessment protocols of study participants and upload the pdfs of the scanned copies to a secure shared folder on the VA network that is only accessible by the research staff. Designated research assistants at VA Palo Alto will enter data into a password-protected SPSS database. All baseline and 6- and 12-month assessments will be kept in locked file cabinets. A copy of this self-report data will also be stored on the project folder in VINCI.

Research assistants will receive training in areas of data security, data collection and data entry to ensure uniformity. Access to the SPSS database will be restricted to only those who are deemed necessary for project execution. The servers housing the study database and baseline and follow-up assessments will be located at a secure VA facility and housed behind the VA firewall on VA-owned and-maintained servers.

In case of improper use or disclosure of study data, the facility's ISO and Privacy Officer, and the individual's direct supervisor will be notified immediately per VA Directive and Handbook 6500. According to the VHA Records Control Schedule, research data will be destroyed 6 years after cutoff but may be retained longer if required by other federal regulations. The cutoff date is at the end of the fiscal year after completion of the research project.

Quality control checks and clinical monitoring procedures will be implemented to ensure that data entered into the study database is correct.

**Data and safety monitoring.** This project will be overseen by the HSR&D Data and Safety Monitoring Board, which reviews multisite interventional studies. This Board provides guidelines on plans for monitoring the safety of participants and the accuracy and integrity of the data, and reviews participant recruitment and enrollment. We will comply with all Board guidelines and requirements.

As noted above, a number of safeguards are in place to protect the confidentiality of subjects. All project personnel will be required to complete mandatory VA trainings related to the use of human subject data including (a) Good Clinical Practices and Human Subjects, (b) VA Privacy, (c) VA Cyber Security Awareness, and (d) the VA Information Security 201 online training courses and regulations for data transportation, storage, and destruction. All data will be stored electronically in a restricted access folder and will be stored on VA-issued, supported, and password-protected computers. Only approved project personnel will have access to these data. For the current study, we will retain subject contact information and data for future research studies. To this end, during the informed consent process and HIPAA authorization we will request permission from subjects to retain their contact information and data after the study is completed and to re-contact them about participating in future VA research projects. This data

will be stored in a to-be-established data repository, which will be set up in accordance with VHA Handbook 1200.12. The IRB of record for VA Palo Alto (Stanford Human Subjects Committee) and the VA Palo Alto Research & Development Committee will oversee the to-be-established data repository.

In addition to receiving training on data security and privacy issues, the sensitive nature of the information being collected will be emphasized with all project staff. Further, all matching of participants with their criminal data will be overseen directly by the site PIs to ensure that the utmost caution is being taken to protect privacy. It should be reiterated that this study is recruiting JIVs from VA MH RRTPs, and is not recruiting Veterans from incarcerated settings. However, we plan to conduct follow-up assessments at 6- and 12-months post-baseline, and at those time points some participants may be incarcerated.

## **8.0 Communication Plan**

As PI, Dr. Blonigen will oversee and ensure the integrity of all aspects of the proposed work. Drs. Blonigen and Smelson have a longstanding, productive, and collegial partnership in mental health services research projects. As a leadership team, they will oversee all planning of dataset construction, analyses, and manuscript preparation, and will ensure that all required approvals have been obtained. The leadership team, data analysts, and research assistants will meet on a weekly basis to facilitate work flow, quality assurance, and momentum during the project start-up period and first month of study enrollment. Drs. Blonigen, Smelson, and Cucciare (as Local Site Investigators for Palo Alto, Bedford, and Little Rock, respectively) will facilitate and supervise the data collection within their respective MH RRTPs and participate fully in scientific decision making related to study development, fidelity, and the synthesis and dissemination of results.

After this time period, all-staff phone conferences will occur bi-weekly. These meetings will function as check-ins to ensure that the study is being conducted according to the Central IRB-approved protocol. In the event of more urgent needs, such as Serious Adverse Events or Unanticipated Problems, the leadership team will contact the Local Site Investigators directly. Throughout the study duration, Drs. Blonigen and Smelson will hold a separate weekly meeting with the Project Manager to discuss progress on the specific tasks in the project timeline. Any issues raised during these meetings will be emailed to all project team members for feedback and included on the agenda for the next all-staff phone conference.

In the event of improper use or disclosure of PHI, the relevant site's Information Security Officer and Privacy Officer will be notified within one hour of the improper use or disclosure and all local policies will be followed. This event will also be communicated to the Local Site Investigators and the Principal Investigator. When a researcher leaves a study team (either by transferring to another position within the VA or leaving the VA), their access to these secure folders is removed by the Principal Investigator. Local check out policy demands that individuals be removed from all research protocols, keys for files and offices are turned in, and electronic access to research files is revoked prior to leaving the facility.

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