Brief Intervention for Justice-Involved Substance Users: Harnessing Mechanisms of Change

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Study Design

D.3. Overview. We propose a rigorous RCT using a matched-pairs design to test *a priori* hypotheses based on the findings of Preliminary Study 2, while investigating the mechanisms by which people change. In line with renewed national efforts to promote reproducible science, this study is, among other things, an attempt to replicate the primary findings of our published work in a larger sample. We incorporate appropriate blinding, and validated, multi-method measurement of constructs. We will compare the efficacy of BMI+SC versus SC across two groups: a) individuals with low/moderate affective psychopathy (affective score < 5) and, b)individuals with high affective psychopathy (affective score > 5). In Session One, individuals who are within their first three weeks at MCPS will be recruited and briefly screened for substance use. Individuals who report substance use once per week or more and meet the Drug Abuse Screening Test cutoff score of 3 or higher[51] will continue in the study. Session Two (Baseline Assessment A) will involve a brief assessment of general psychopathology and detailed assessment of psychopathy and frequency of use of a range of substances. Baseline assessment B will include assessment of putative mediators (self-regulation and commitment to change), along with an assessment of treatment services use over the past 6 months. After Baseline Assessment B, participants will be randomized (coin toss) to either BMI+SC or SC in pairs that are matched according to affective psychopathy level. That is, two individuals with low/moderate affective psychopathy will be randomized (one each) to either BMI+SC or SC. The same will occur with individuals who are high in affective psychopathy. The next session will occur as close to baseline as possible, followed by sessions at 2, 4, and 6 weeks post-baseline. These meetings will involve assessments of frequency and type of substance use (both groups), and the delivery of our BMI (treatment group only). The outcome variables will be 1) frequency of substance use (proximal; percent days abstinent at 6 months) and 2) violent criminal recidivism (distal; charges at 12 months).

D.3.1. Sample. A total of 536 participants will be recruited and randomized to either the BMI+SC or SC condition during the first four and a half years of the study. The proposed sample size is feasible based preliminary data (i.e., approximately one eligible participant per recruiting day). We will screen approximately 545 participants per year (in 1:1 format). Based on preliminary data, 22% of these participants (n=119) will meet eligibility criteria for the study. We estimate attrition during follow-up at approximately 25% based upon Preliminary Study 2, leaving approximately 91 participants per year (or a total of 416 across 4.5 years) for analysis.

D.3.2. Rationale for standard care control group. Ultimately it is important to determine whether the BMI is efficacious relative to a specific active comparison condition. However, it is first necessary to determine whether the BMI+SC works at all compared to SC, taking into account affective psychopathy scores. Approximately 50% of all MCPS clients are mandated through the court system to complete substance abuse treatment, though the number who do so is lower. For the proposed study, the SC condition will include individuals who receive levels of non-study intervention that vary widely, from none to substantial. This real world condition provides the potential for useful generalization of results to other supervision programs, and is an appropriate comparison for assessing a brief intervention that may best serve as an adjunct to SC. The SC condition will consist of no research-related intervention beyond the baseline assessment session, but we will measure and analyze all non-study treatment participation carefully. Individuals in MCPS do not receive substance use services onsite, though some are referred to community providers for treatment. For anyone involved in non-study treatment, we will measure number of sessions and type of treatment in order to ensure that comparisons between BMI+SC and SC take into account all extra-study treatment.

D.4. Overview of Study Appointments

D.4.1. Recruitment. After hearing an announcement in which the study is outlined, individuals who are within their first two weeks of the program, are 18 and older, can speak English, and are interested in participating will meet with study personnel individually. Those who provide informed consent will be enrolled. The informed consent procedure will include a detailed description of study procedures. For individuals with poor reading ability, as determined by having participants read the first paragraph of the consent form aloud, all written materials will be read by study personnel. See Appendix C for a table of measures and the administration timeline.

D.4.2. Session 1: Substance use screen. The screening sessions will be administered in 1:1 format. After filling out a demographic information form, participants will be administered three brief self-report measures to characterize substance use: a 12-item measure of the frequency of use of specific drugs, the Drug Abuse Screening Test (DAST)[53] and the Alcohol Use Disorders Identification Test (AUDIT).[56] Participants will be paid $5. Individuals who indicate a frequency of substance use of once per week or greater during the past 6-months and have a DAST score > 3 are eligible for the RCT, with the exception of persons who exhibit severe psychotic symptoms or significant cognitive impairment during the initial or baseline assessments.

D.4.3. Sessions 2 and 3: Baseline Assessments A and B. Participants who qualify will complete two baseline assessment sessions, scheduled within one week of each other, to gather thorough multi-method data while minimizing subject burden. For *Baseline A* we will administer the Timeline Followback Interview (TLFB)[57] to measure drug and alcohol use frequency in the past 90 days and the 125-item PDSQ[51] to screen for mental disorders. We will then administer a standard psychopathy interview - a semi-structured interview designed to gather information regarding education, relationships, family life, and criminal, medical, and work history. The Psychopathy Checklist-Revised (PCL-R)[31] will be scored based on this interview and a review of the participant's MCPS file. Following the interview, all participants will receive the names and numbers of drug and alcohol treatment providers, and will be paid $20 for their time. *Baseline B* will be primarily for the initial assessment of mediators of behavioral change. First, we will administer the Self-Regulation Questionnaire[58] and the Readiness Ruler.[59] Participants will then complete a behavioral task – the Balloon Analogue Risk Task (BART)[60] as a second method of assessing self-regulation. Finally, we will gather extensive information on nonstudy treatment utilization using the Economic Form-90,[61] a valid interview that obtains information about recent health services use. This will include treatment type (e.g., medication vs. psychosocial, individual vs. group, and substance use vs. mental health). This information will be supplemented with information on treatment modality collected from area substance use treatment centers. For example, of the four service providers contacted by the P.I. since the initial submission, all provided data on modality (12-step/abstinence based vs. cognitive behavioral or integrative). Following Baseline B, participants will be randomized in matched pairs – based on affective psychopathy group – to BMI+SC or SC.

D.4.4. Brief Motivational Intervention and/or Assessment. A therapist who is blinded to psychopathy status will conduct the intervention, which was based on Bernstein et al.'s BMI[14,62] with cocaine and heroin users in a clinic setting. Prior to Preliminary Study 2, we adapted this manual to improve its relevance to justice-involved substance users in a supervision program. First, due to generally low levels of education and the acuity of our participants needs, we increased the initial session length to approximately 40 minutes in duration (up from Bernstein et al.'s 20-30 minutes) and added three follow-up sessions. This provides more time for rapport building and reinforcement of participant change talk. Additionally, we added an explicit acknowledgement of our non-judgmental stance at the outset of each session in order to distinguish treatment from punishment and us from criminal justice professionals in non-treatment roles. Because of high levels of psychiatric disorder in offender populations, we also added feedback regarding measured psychiatric problems in order to help individuals understand the link between mental health issues and substance use in their lives.
Participant feedback during Preliminary Study 2 indicated satisfaction with the intervention. Based upon recent empirical literature, we have further updated the BMI for the current proposal in order to

enhance the efficacy of the intervention and perhaps broaden its therapeutic effects to more participants. This update involves dropping the use of a decisional balance exercise in order to decrease the amount of time spent talking about positive drug use experiences – a practice that may be detrimental and may elicit cravings.[63,64] Our BMI manual (Appendix B) includes the following steps: establishing rapport, asking permission to discuss drugs and providing feedback regarding the drug use assessment, exploring personal consequences of drug use, eliciting the gap between real and desired quality of life, and discussing readiness to change. The therapist then negotiates a written action plan, during which the participant is supported with empathy, verbal reinforcement,
information about drug abuse and treatment providers, and a referral for treatment.[15] Continuing care is important for substance users[65] and data show that having more than one BMI session significantly enhances outcomes,[66] thus we will include brief (20-30 minutes), flexible, follow-up intervention sessions (Weeks 2, 4, and 6). Each follow-up session will be preceded by an assessment of substance use since the last session by personnel who are blind to psychopathy and treatment status. The Week 6 follow-up will also include readministrations of the BART and Self-Regulation Questionnaire (mediators) to assess change in self-regulation since baseline. Individuals in the BMI+SC and SC conditions will receive the same number of assessments and the same compensation ($50) for assessment time. Individuals in both the BMI+SC and SC conditions will be assessed for substance use and treatment contacts at Weeks 2,4 and 6 and again at 6 months.

D.4.5. Follow-up assessment procedures. Following the initial assessment, participants will provide detailed identifying information and locator data, including contact information for significant others whom the participant is comfortable having the research team contact. The following additional steps will be taken in order to minimize attrition as suggested by the literature on treatment retention of substance abusers and justice-involved people.[67,68] 1) The interviewer will invite the participant to contact him/her regarding any changes in address, phone number, or other contact information. 2) Participants will attend follow-up appointments either at MCPS or the University of Rochester Medical Center and will be provided with ample compensation for participation and to cover travel and parking costs. 3) Participants will sign releases that allow treatment providers and the Sheriff's department to be contacted. Should the need arise to contact these entities in an effort to locate a subject to schedule a follow-up session, the interviewer will provide only the general explanation that the participant is enrolled in a survey at URMC and "gave me permission to contact you in case I lost touch." 4) Participants will be contacted in advance of appointments in order to confirm. 5)
Individuals who are in jail at scheduled follow-up times will have assessment sessions take place at the jail (as in preliminary study 2). BMI sessions will not be conducted at the jail due to privacy concerns.

D.5.1. Objective measures. Due to the potential for underreporting of substance use, we will obtain breathalyzer and urinalysis drug screen results at each follow-up using Varian Testcup Pro 5, which provides results for THC, methamphetamines, cocaine, benzodiazepines, and morphine. Results will be used to provide an objective measure of substance use to be incorporated in a secondary analysis. For the assessment of recidivism, The New York State Division of Criminal Justice Services (DCJS) maintains a database of criminal charges and convictions across the state. We will contract with DCJS to provide data at 12 months following the intervention or baseline assessment. Additionally, MCPS maintains a database of county-wide charges and convictions. Because each database does not always capture all official charges and convictions, they will be combined for maximum sensitivity (as in Preliminary Study 1). Criminal charges will be used as the primary measure of recidivism. Finally, recent involvement in non-study interventions will be assessed at baseline as a potential confound, and during follow up for descriptive purposes. Based on the results of the primary analyses, this data may also be used in exploratory analyses to determine whether BMI+SC increased substance abuse services utilization. The Coordinated Care Services, Inc. (CCSI) database will provide a novel
way to gain objective information about participant treatment contacts—including substance abuse treatment—during the follow-up period. This health surveillance database is maintained by the Monroe County Office of Mental Health and was utilized in Preliminary Study 1. This database is used to track county-wide service contacts, enabling us to obtain services use data even for individuals who are lost to follow up. Moreover, we are able to cross-reference the objective database with our self-report

measure of non-study treatment for increased sensitivity and to check the validity of self-report treatment data.

D.5.2. Assessing Mediators. We will conduct a thorough, multi-method assessment of commitment to
change and self-regulation as mechanisms of change. Commitment to change. 1) We will code change talk that occurs in BMI sessions using the Client Language Easy Rating (CLEAR) coding sheet.[69] Audiotaped sessions will be transcribed and coded for the proportion of participant change talk: change talk/(change talk+sustain talk+neutral), yielding the percentage of speech utterances that are change talk. 2) The readiness ruler, an efficient and reliable measure of motivation to change[59], will be used at baseline and following each intervention session for an assessment of readiness to change. Self-Regulation. The Self-Regulation Questionnaire[58] will be administered during the screening session and after each intervention session to assess increases in self-regulation that have occurred. The BART,[60] a computerized behavioral task, will provide a second method of assessing self-regulation and will be administered after the last intervention session.

D.6. Personnel and training. The multidisciplinary research team from Preliminary Study 2 remains intact, including the study coordinator (Melissa Parkhurst, BA), and the study therapist (Nicole Trabold, Ph.D.,LCSW). During the first year of the award period, the P.I. (a psychologist with extensive experience with M.I.) will hire a third therapist in order to ensure that we adequately study any therapist effects. The P.I. will conduct training on the BMI that involves four, four-hour seminars. Materials will include Miller and Rollnick's text on MI[15] and the intervention manual (Appendix B.) The P.I. will then conduct therapist BMI training sessions at MCPS. The Motivational Interviewing Treatment Integrity (MITI) code[70] will be used to assess treatment fidelity during these observations. The MITI measures therapist behaviors, yielding both global scores and behavior counts that indicate whether a therapist is delivering an MI-consistent intervention. Once each therapist demonstrates adequate treatment adherence for three straight observed sessions, he or she will begin conducting sessions alone. The P.I. will serve as the primary clinical supervisor for Dr. Trabold and an
additional therapist, and will conduct a minimum of 20% of BMI sessions. The project coordinator has extensive training in all baseline assessments and how to assign subjects to treatment conditions. New personnel will receive intensive PCL-R training from the P.I. Psychopathy interviews will be audio-recorded in order to measure interrater reliability and BMI sessions will be audio-recorded to assess MI-related fidelity and provide data for the linguistic analysis of change talk.