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# A randomized, open label trial of methadone continuation versus forced withdrawal in a combined US prison and jail: Findings at 12 months post-release

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ABSTRACT

Recently, incarcerated individuals are at increased risk of opioid overdose. Methadone maintenance treatment (MMT) is an effective way to address opioid use disorder and prevent overdose; however, few jails and prisons in the United States initiate or continue people who are incarcerated on MMT. In the current study, the 12 month outcomes of a randomized control trial in which individuals were provided MMT while incarcerated at the Rhode Island Department of Corrections (RIDOC) are assessed. An as-treated analysis included a total of 179 participants—128 who were, and 51 who were not, dosed with methadone the day before they were released from the RIDOC. The results of this study demonstrate that 12 months post-release individuals who received continued access to MMT while incarcerated were less likely to report using heroin and engaging in injection drug use in the past 30 days. In addition, they reported fewer non-fatal overdoses and were more likely to be continuously engaged in treatment in the 12-month follow-up period compared to individuals who were not receiving methadone immediately prior to release. These findings indicate that providing incarcerated individuals continued access to MMT has a sustained, long-term impact on many opioid-related outcomes post-release.

## 1. Introduction

Prevalence of opioid use disorder (OUD) is exaggerated among those who are incarcerated (Mumola and Karberg, 2006). Just over 23% of state prisoners report ever using heroin or other opiates and 13% report regular use prior to incarceration (Mumola and Karberg, 2006). In addition, people who have recently been incarcerated are at extreme risk of overdose during community re-entry (Binswanger et al., 2007). A recent study that investigated all causes of mortality of people who were formerly incarcerated in Washington State found that overdose was the number one cause of death (Binswanger et al., 2013).

Methadone-maintenance treatment (MMT), the combination of behavioral therapy, counseling and methadone provision, is an effective, evidence-based approach to address opioid use disorder and overdose (Connock et al., 2007). Numerous studies have documented the far-reaching benefits to implementing MMT in correctional populations, including post-incarceration reductions in illicit opioid use (Mattick et al., 2009; Kinlock et al., 2009), re-incarceration (Deck et al., 2009; Larney et al., 2012), mortality and overdose (Degenhardt et al., 2011; Kerr et al., 2007), and HIV risk behaviors (MacArthur et al., 2012) among others (Rich et al., 2015, Zaller et al., 2013, McKenzie et al., 2012, Heimer et al., 2006; Dolan et al., 2003).

In the United States (US), there are over 3200 local and county jails and 1800 state and federal prisons, but few facilities offer addiction treatment using MMT (Vestal, 2016; Lee et al., 2015). In 2008, less than 0.1% of the total prison population received any form of buprenorphine or MMT (Larney and Dolan, 2009), and, while 28 state prison systems make MMT available to those who are incarcerated, a majority restrict

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treatment to special populations (e.g., pregnant women; Nunn et al., 2009).

When MMT or other forms of medication for addiction treatment (MAT) (Wakeman, 2017; e.g., buprenorphine) are not provided in the correctional setting, individuals who are addicted to opioids experience symptoms of withdrawal. Opioid withdrawal can include severe physical discomfort and psychological distress, risk of suicide, and leads to loss of opioid tolerance, thereby increasing risk of fatal and non-fatal overdose post-release (Merrell et al., 2010). Also, while the current literature points to the clear benefit of providing MMT during incarceration and linkage to treatment in the community, less is known about the long-term effects of MMT access during incarceration.

The objective of the current study was to identify the long-term effects of providing access to MMT for people who are incarcerated. From 2011–2014, we conducted a randomized control trial to assess the impact of continued MMT versus forced withdrawal from methadone in people who were incarcerated for six months or less, on fatal and non-fatal overdose, substance use, emergency department use, treatment engagement in the community, and HIV risk behaviors such as injection drug use and transactional sex. Baseline results indicated that forced withdrawal from MMT reduced the likelihood of MMT engagement post-release in the community (Rich et al., 2015). In the current study, we present outcomes measured at 12 months following release.

## 2. Methods

### 2.1. Study design

The study was conducted at the Rhode Island Department of Corrections (RIDOC), a unified, statewide prison and jail system. All participants gave written informed consent. This study was approved by the Institutional Review Board of the Miriam Hospital in Providence, Rhode Island (RI), and the RIDOC Medical Research Advisory Group. In addition, the study was reviewed by a data safety monitoring board every six months for the first two years of recruitment, then once per year until the study ended. This trial is registered with ClinicalTrials.gov (number NCT01874964).

Inclusion criteria for the study included being incarcerated for at least one week and no more than six months and having been engaged in MMT treatment prior to incarceration. At intake, individuals reported to RIDOC nursing staff whether they were enrolled in a MMT program before incarceration. Nursing staff then confirmed dosing with the community provider. Nursing staff and MMT counselors provided study information to eligible participants. The name and facility location of individuals who expressed interest were forwarded to the research staff who then followed up with an in-person visit that occurred within seven days.

### 2.2. Enrollment and randomization

After consent was obtained, participants were randomly assigned (1:1) using a computer-generated random permutation to either a) continued MMT or b) tapered withdrawal from methadone after the first week of incarceration, the standard of care at the RIDOC at the time. Study staff worked in tandem and randomly assigned participants to each group—meaning that separate study staff members completed enrollment and randomization. The same staff member who enrolled the participant followed up with him or her in the community post-release. Because there were more men than women and few racial minorities were enrolled in MMT and incarcerated during the study period, urn randomization was used to stratify individuals on the basis of sex and race. Urn randomization is appropriate, given that it can balance groups with several covariates and has a low risk of experimenter bias or manipulation (Wei and Lachin, 1988).

### 2.3. Procedures

Participants in the MMT continuation group were maintained on methadone during incarceration, with adjustments made to their dose as clinically indicated. Participants who were receiving a stable dose were continued on the same dose. Those participants whose doses were being adjusted at the time of incarceration or who had symptoms caused by doses that were either too low or too high, had adjustments made in accordance with standard clinical practices, usually in collaboration with their community methadone clinic.

Participants who were assigned to standard care (meaning forced withdrawal from methadone) completed the RIDOC's standard protocol for MMT upon entry, which, at the time of the study, included continuation of entry dose during the first week of incarceration followed by a tapered withdrawal schedule (e.g., an entry dose of > 100 mg would be reduced by 5 mg per day to 100 mg, then reduced by 3 mg per day to 0 mg). Since the standard taper protocol typically lasted 4–6 weeks or longer, participants in the forced withdrawal group could still be receiving a daily dose of methadone at the time of release, dependent on the length of their incarceration and starting dose (e.g., if they were incarcerated for two weeks). Upon discharge (regardless of study condition), all participants were assisted with transportation, scheduling, and financing for their first MMT appointment in the community.

All research assessments were administered via face-to-face interviews. At enrollment, we asked participants to provide multiple ways to contact them in the community to increase our chances to conduct follow-up interviews. Participants provided thorough contact information and information about places they liked to "hangout". This information was used if phone and mail attempts went unanswered and was particularly useful for unstably housed participants. To accommodate transportation issues, we provided cab or bus fare and met participants in locations convenient for them to complete the interview. In addition, we provided participants with business cards with interview dates, reimbursement amount, and research staff contact information and reminded them of assessments via mail and phone. Research assessments were conducted at one, six, and 12 months post-release. All outcomes reported herein are from the 12-month follow-up interview.

All follow-up interviews took place at a location most convenient to the participant, such as a private interview space located at The Miriam Hospital or one of the treatment facilities, a fast food restaurant, or a participant's home. Privacy and safety concerns were part of staff training and were discussed in staff meetings. Follow-up interviews, on average, lasted about thirty minutes. After each completed assessment, participants received $20. Additionally, participants could receive $5 for checking in between the one month and six-month study visit and between the six and 12-month study visit.

### 2.4. Study population

We enrolled participants between June 2011 and April 2013. A detailed description of the study population and one-month outcomes are published elsewhere (Rich et al., 2015). At baseline, there were a total of 223 participants, and 179 completed a 12-month follow-up (80.3% retention). Of the 44 participants for whom no 12-month follow-up interviews were completed, four died of an overdose (two were on MMT at release and two were not) and one participant died from violent causes. Seven participants were continuously incarcerated between the six- and 12- month assessments, and did not complete a 12-month interview. One participant refused participation in the 12-month assessment, and we were unable to contact the remaining 31 participants. There were no statistically significant differences between those who completed a 12-month interview and those who were lost to follow-up (data not shown). A total of 51 participants were released from incarceration after having been completely tapered from methadone. These participants, on average, spent 52 days without methadone