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Methadone treatment of arrestees: A randomized clinical trial

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Abstract

Background: Opioid use disorder is common among detainees in US jails, yet methadone treatment is rarely initiated.

Methods: This is a three-group randomized controlled trial in which 225 detainees in Baltimore treated for opioid withdrawal were assigned to: (1) interim methadone (IM) with patient navigation (IM + PN); (2) IM; or (3) enhanced treatment-as-usual (ETAU). Participants in both IM groups were able to enter standard methadone treatment upon release, while ETAU participants received an assessment/referral number. Follow-up assessments at 1, 3, 6, and 12 months post-release determined treatment enrollment, urine drug testing results, self-reported days of drug use, criminal activity, and overdose events. Generalized linear mixed modelling examined two planned contrasts: (1) IM groups combined *vs.* ETAU; and (2) IM + PN *vs.* IM.

Results: On an intention-to-treat basis, compared to ETAU, significantly more participants in the combined IM groups were in treatment 30 days post-release, while the IM + PN *vs.* IM groups did not significantly differ. By month 12, there were no significant differences in the estimated marginal means of enrollment in any kind of drug treatment (0.40 and 0.27 for IM + PN and IM groups, respectively, compared to 0.29 for ETAU). There were no significant differences for either contrast in opioid-positive tests, although all groups reported a sharp decrease in heroin use from baseline to follow-up. There were five fatal overdoses, but none occurred during methadone treatment.

Conclusion: Initiating methadone treatment in jail was effective in promoting entry into community-based drug abuse treatment but subsequent treatment discontinuation attenuated any potential impact of such treatment.

Keywords

Interim methadone treatment; Patient navigation; Criminal justice; Jail; Overdose death; Opioid use disorder

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Role of authors

Drs. Schwartz, Jaffe, and O'Grady designed the study. Drs. Schwartz, Jaffe, and Kelly drafted the manuscript. Drs. O'Grady and Mitchell and Ms. Sharma provided edits to the draft. Dr. Kelly conducted the data analysis under the supervision of Dr. O'Grady. Ms. Sharma played a role in collecting participant data. All authors have approved the final manuscript.

Declaration of Competing Interest

Dr. Schwartz reports consulting for Verily Life Sciences, Ltd. The other authors report no conflicts.

1. Introduction

Methadone maintenance treatment (MMT) for opioid use disorder (OUD) is associated with decreased opioid use (Mattick et al., 2009) and reduced drug-related mortality (Sordo et al., 2017). OUD is prevalent among detainees in US jails (Boutwell et al., 2007; Bronson et al., 2017). Relapse to illicit opioid use upon release is common and is associated with elevated risk for overdose death (Merrall et al., 2010; Pizzicato et al., 2018). In the US, few jails initiate MMT for individuals with OUD who are out-of-treatment at arrest. There are several barriers to implementing MMT in jails, among which is cost. One way to reduce cost would be to provide MMT without routine counseling (termed “interim treatment”) which is effective in treating patients in the community who otherwise would be unable to enter MMT (Gruber et al., 2008; Schwartz et al., 2006; Yancovitz et al., 1991).

There is a paucity of research examining the effectiveness of initiating MMT for detainees who were not enrolled in such treatment at the time of arrest. While there have been several randomized trials of pre-release methadone treatment for prisoners compared to various types of controls (Moore et al., 2019), only Magura et al. (2009) studied recent arrestees who had not been in methadone treatment prior to arrest. In that trial, participants were randomly assigned to receive either buprenorphine or methadone prior to release. The buprenorphine treatment group compared to MMT group was significantly more likely to attend treatment in the community. Only 23% of those started on methadone entered opioid agonist treatment after release.

One approach that might increase post-release MMT entry would be to employ an assigned helper (“patient navigator”) to work with patients started on methadone while incarcerated. The present study, described elsewhere (Schwartz et al., 2019), was a parallel, three-group randomized clinical trial comparing: (1) initiating interim methadone in jail with a patient navigator; (2) initiating interim methadone in jail without a patient navigator; and (3) enhanced treatment-as-usual. In contrast to the study by Magura and colleagues (2009), a concurrent control group in the present study did not receive agonist maintenance treatment during incarceration, urine drug testing was conducted, and participants were followed for a full 12 months (rather than 3 months) following release.

2. Methods

2.1. Participants

Individuals 18 years old were eligible if they: (1) met DSM-5 OUD criteria; (2) were detained 48 h; (3) had a charge for which, if found guilty, would likely result in a sentence of less than one year; (4) were receiving opioid withdrawal treatment; (5) provided informed consent; and (6) planned to live in the Baltimore region upon release.

Individuals were excluded if they were: (1) receiving community-based methadone or buprenorphine treatment; (2) medically/psychiatrically unstable; (3) pregnant; or (4) receiving treatment for moderate/severe alcohol or sedative hypnotic withdrawal.

The study was approved by the Friends Research Institute's IRB, Western IRB, and the US Office of Human Research Protection.

2.2. Recruitment and randomization

Between 12/16/14 and 10/12/17, the Baltimore City Detention Center's medical staff referred patients receiving medically-supervised opioid withdrawal treatment to the study's Research Assistants (RAs) for screening and informed consent. The RAs administered baseline assessments and obtained the patient's medical record for review by the Principal Investigator. All participants were given information about substance misuse, overdose prevention, and the local community treatment assessment and referral helpline number. The RAs then assigned participants to Group (1:1:1 basis) within gender in blocks of 3, 6, or 9 by opening the next opaque, sealed and numbered randomization envelope. The random allocation sequence was generated by the study's Statistician using random permutation procedure.

2.3. Treatment in detention

2.3.1. Enhanced Treatment as Usual (ETAU)—ETAU consisted of a medically-supervised withdrawal with methadone over the course of $7 \pm$ days and information on: harms associated with illicit drug use, the city's treatment referral helpline number, and overdose prevention.

2.3.2. Interim Methadone (IM)—IM treatment consisted of an individualized gradual methadone dose induction, initiated at the participant's request and physician's approval, to a target of up to 60 mg daily. Treatment was provided through the Detention Center's Opioid Treatment Program (OTP), which, for over a decade, has continued MMT for detainees who were enrolled in MMT at arrest and only initiated MMT for pregnant women. Routine counseling was not provided, though mental health treatment was available. Participants were able to continue MMT in jail unless they were sentenced and transferred to prison or had a serious rule infraction, whereupon they received a gradual dose reduction. IM participants chose one of four OTPs they wished to attend after release. The Detention Center's nurses arranged for continued methadone administration for the day following release. The OTP scheduled an intake for formal admission for participants who attended the program within three days of release and admitted participants were offered the OTP's usual services (including dose adjustments and counseling).

2.3.3. Interim methadone with patient navigation (IM + PN)—IM + PN included IM treatment plus access to a patient navigator. Prior to the present study, the patient navigator, who was not a recovering or formerly incarcerated person, had been trained for 24 h in navigation and worked on Project Hope (CTN 0049; Metsch et al., 2016). She was trained eight hours further for this project, which used a similar navigation approach of strengths-based case management that incorporated motivational techniques (Hall et al., 2002). The navigator's activities were guided by a manual based on prior work (Metsch et al., 2016; Sorensen et al., 2005). The navigator met with participants once during detention to devise a post-release plan. In the community, the navigator offered eight or more case management sessions over three months to address barriers to entering and receiving OUD

treatment, and to help obtain basic needs such as ID cards, bus passes, and other services. A modest fund was available to the patient navigator for obtaining IDs and bus passes.

2.4. Assessments

Participants were assessed at baseline and 1, 3, 6, and 12 months after release between 3/10/15 and 3/8/19. Assessments included the Addiction Severity Index (ASI; McLellan et al., 1992), which obtained self-reported past-30-day opioid and cocaine use and criminal activity at each time point. A modified World Mental Health CIDI (WHO CIDI, 2017) assessing DSM-5 criteria for OUD and Cocaine Use Disorder (CUD) was administered at baseline and at 3, 6, and 12 months post-release. OUD treatment status and any non-fatal overdose(s) and hospitalizations were self-reported at each follow-up. Urine testing was conducted at each follow-up (unless the participant was incarcerated or in rare instances, had relocated at some distance from Baltimore and were interviewed by telephone) for opioids, oxycodone, methadone, buprenorphine, and cocaine. Methadone- and buprenorphine-positive tests were not treated as “opioid-positive” if the participants reported receiving these medications for treatment. Participants received no payment at baseline and \$30 for each follow-up interview.

2.5. Outcome measures

The two primary outcome measures were enrollment status (yes/no) in any OUD treatment 30 days post-release and opioid testing results (positive/negative) at the 1-, 3-, 6-, and 12-month follow-up time points. Secondary outcomes included treatment status, cocaine urine testing results, and DSM-5 OUD diagnosis (measured across the 12-month follow-up period), and DSM-5 Cocaine Use Disorder diagnosis and self-reported past-30-day number of days of heroin use, cocaine use, and criminal behavior (measured from baseline through follow-up). Participants provided release of information to obtain hospital records and death certificates were obtained.

2.6. Aims and hypotheses

We hypothesized that the IM + PN and IM Groups combined would have outcomes superior to ETAU, and that IM + PN would have outcomes superior to IM.

2.7. Statistical analysis

Analyses were conducted on an intention-to-treat (ITT) basis, which included participants released directly from the Detention Center as well as participants sentenced and transferred to prison who were eventually released to the community. A Generalized Linear Model (GLiM) was used to analyze outcomes measured at only one time point, while a Generalized Linear Mixed Model (GLiMM) was used to analyze outcomes measured repeatedly. A modified intention-to-treat analysis that excluded participants who were sentenced and transferred to prison was also conducted. Effects included in the two models were gender as a moderator, and age, prior lifetime MMT (yes/no), and self-reported number of days of cocaine use in the past 30 days at baseline as covariates.

A completers analysis compared outcomes for participants assigned to the two IM groups who reported whether or not they were enrolled in methadone or buprenorphine treatment at *all* four follow-up assessment time points (completers $n = 28$; non-completers $n = 64$).

2.7.1. Missing data—For outcomes measured repeatedly, GLiMM analyses were conducted using maximum likelihood approach to estimation, for which data are assumed to be missing completely at random (MCAR) or missing at random (MAR). Maximum likelihood provides better estimates in terms of reduced bias and sampling variability when data are missing at random than listwise or pairwise deletion (Enders, 2001; Janisse et al., 2014). In addition, maximum likelihood yields estimates that are equivalent to estimates generated by multiple imputation, and has the power to detect smaller effect sizes (Graham et al., 2007; Janisse et al., 2014). For outcomes measured at only a single time point, missing data were not estimated or replaced.

2.8. Planned contrasts

There were two planned contrasts of primary interest. In the case of the GLiM analyses, there were two orthogonal, single-degree-of-freedom planned contrasts comparing: (1) combined IM + PN and IM *versus* ETAU; and (2) IM + PN *versus* IM, while in the case of the GLiMM analyses, the planned contrasts of interest were the interaction of planned contrasts (1) and (2) $\times$ Time, respectively.

2.9. Power

The final enrolled sample was 225 participants rather than the target size of 300 primarily due to lower than expected arrest rates in Baltimore City related to changes in police policies (Schwartz et al., 2019). This reduction in the number of participants necessitated assuming a Type I error rate (α) of 0.05 in order to achieve reasonable power, resulting in a revision to the original power analysis. There was no change in the study aims, hypotheses, statistical model, or assumptions regarding power calculations beyond the change to the Type I error rate. In this case, power estimates exceeded 0.83, while the effect size f^2 values ranged from 0.040 to 0.060, falling within the “small-to-medium” range (Cohen, 1998).

3. Results

3.1. Intention-to-treat sample

As seen in Fig. 1, 225 individuals were randomly assigned to and received their allocated intervention in the Detention Center. Prior to release, 15 of the 75 (20.0%) IM + PN participants and 11 of the 74 (14.9%) IM participants discontinued methadone, mostly due to having been sentenced; they were tapered off methadone prior to transfer to prison. Such participants, if later released from prison, were sought for interview and included in the intention-to-treat sample through March 8, 2019. There were no significant differences among Groups in terms of their baseline characteristics ($ps > 0.05$; see Table 1).

3.1.1. Interventions—Participants remained in detention a median (range) of 37 days (0–247 days) and 42% of the participants who were not sentenced and transferred were released within 30 days. The median (range) methadone dose at release for IM + PN and IM

participants was 40 mg (10–60 mg) and 40 mg (5–70 mg), respectively. The median (range) doses at 1-, 3-, 6-, and 12-months post release was 55 (20–90), 60 (30–90), 70 (30–135), and 65 mg (20–145), respectively. The median number (range) of patient navigation sessions delivered over the initial three months following release was 3.0 (0–15).

3.2. Primary outcomes

3.2.1. OUD treatment status 30 days post-release—Within 30 days of release, 49 (80.3%) IM + PN, 32 (57.1%) IM, and 1 (2.0%) ETAU participants reported having received at least one methadone dose in the community. Table 2 shows the 1-month treatment status by Group for all participants interviewed for their 1-month follow-up after release from detention or prison. Compared with the ETAU group, the combined IM groups that were assigned to begin methadone in detention were significantly more likely to be enrolled in any type of OUD treatment at 1-month follow-up [contrast mean difference=−0.39, $p = 0.001$ (see Table 3)]. However, we found no significant difference between the two IM groups (IM + PN *vs.* IM; contrast mean difference=−0.03, $p = 0.84$). No significant gender differences were found in enrollment in OUD treatment. However, compared to younger participants, older participants were significantly more likely to be enrolled in any treatment at the 1-month follow-up ($p = 0.014$).

3.2.2. Opioid urine testing—The number of urine specimens varied by time because not all participants were located at each follow-up, and specimens were not collected at interviews conducted during subsequent incarceration, nor for the few interviews conducted by phone. Estimated marginal means for the Group $\times$ Time interaction effect for opioid testing results are presented in Table 4. The statistical tests for the planned contrasts and all main effects are shown in Table 5.

We found no significant differences for opioid-positive testing results over the 12-month follow-up period between the two combined IM groups *vs.* ETAU ($p = 0.32$) nor between the two methadone groups (IM + PN *vs.* IM; $p = 0.32$).

3.3. Secondary group $\times$ time outcomes

Table 4 shows estimated marginal means for the Group $\times$ Time interaction effect for the secondary outcomes. Table 5 shows statistical tests for these effects. Planned contrasts by gender will be reported in a subsequent paper.

We found no significant differences in self-reported number of days of heroin or cocaine use, criminal behavior, urine cocaine positive tests, or enrollment in OUD treatment over the 12 month follow-up period ($ps > 0.05$) for the combined IM Groups *vs.* ETAU and for the IM + PN *vs.* IM groups. There were also no significant differences in DSM-5 OUD or Cocaine Use Disorder diagnoses ($ps > 0.05$) for the combined IM Groups *vs.* ETAU or for the IM + PN *vs.* IM groups.

3.4. Other secondary-outcome findings

3.4.1. Self-reported days of heroin use (past 30 days)—There was a Time main effect such that days of heroin use from baseline to follow-up decreased significantly ($p <$

0.001). We also found a Gender main effect with women reporting using heroin on more days than men ($p = 0.03$), and a significant effect for baseline cocaine use: more days of cocaine use prior to incarceration was associated with more days of heroin use at follow-up ($p = 0.002$). Finally, there was a significant Gender $\times$ Time effect ($p = 0.002$). Although both women and men significantly decreased their heroin use from baseline to follow-up, women had significantly more heroin use than men at 1 ($p = 0.012$) and 12 months ($p = 0.038$).

3.4.2. DSM-5 OUD—Older participants were less likely to meet criteria for DSM-5 OUD than younger participants ($p = 0.003$).

3.4.3. Cocaine urine testing—The number of days of cocaine use at baseline was positively associated with the likelihood of having a positive cocaine urine testing result ($p < 0.001$).

3.4.4. Self-reported days of cocaine use (past 30 days)—There were both significant Time and Gender main effects ($ps < 0.001$) with the number of days of self-reported cocaine use decreasing from baseline to follow-up for the total sample, and women reporting using cocaine on significantly more days than men over the course of the study. There was also a significant Gender $\times$ Time interaction effect ($p = 0.02$). Although both men and women reported fewer days of cocaine use from baseline to 1-month follow-up, males decreased their self-reported days of cocaine use by half from baseline to 12-month follow-up ($p < 0.001$), while females' self-reported use from baseline to 12-month follow-up did not decrease ($p = 0.33$).

3.4.5. DSM-5 Cocaine Use Disorder (CUD)—There was a Time main effect with participants less likely to meet two or more DSM-5 CUD criteria from baseline to follow-up ($p < 0.001$). Moreover, more self-reported days of cocaine use at baseline was significantly associated with meeting DSM-5 CUD criteria ($p < 0.001$).

3.4.6. Self-reported days of illegal activity (past 30 days)—There was a Time main effect: self-reported illegal activity dropped significantly from baseline to follow-up ($p < 0.001$). Furthermore, younger age and more of days of cocaine use at baseline were significantly associated with more days of illegal activity ($ps < 0.001$).

3.4.7. Enrollment in OUD treatment status—There was a significant Time main effect for the total sample ($p = 0.046$) indicating that participants who were interviewed at follow-up were less likely to be in treatment at 12-month follow-up than at 1-month follow-up ($p = 0.012$). Nevertheless, the estimated marginal means at the 1-, 3-, and 6-month follow-ups were more than twice as high in the IM + PN and IM groups compared with ETAU (see Table 4).

3.5. Adverse events

Of the 225 participants, 11 IM + PN, 20 IM, and 16 ETAU participants had a total of 77 non-study-related serious adverse events (SAEs; 70 inpatient hospitalizations and 7 deaths), including 19 in the IM + PN, 41 in IM, and 17 in ETAU. There were five fatal opioid overdoses, including 1 IM + PN, 2 IM, and 2 ETAU participants, none of which occurred

during methadone treatment. Three IM + PN participants, 12 IM participants, and 12 ETAU participants reported having a total of 48 non-fatal overdoses, of which only 3 (6.3%) occurred during methadone treatment.

3.6. Modified intention-to-treat (MITT) analyses

A MITT analysis was conducted that included only participants who were released to the community from detention without being sentenced and transferred to prison (*N*s: Baseline = 197; 1-month follow-up = 155; 3-month follow-up = 161; 6-month follow-up = 169; 12-month follow-up = 167). The MITT findings were similar to the ITT findings with regard to treatment status at 1-month follow-up (combined IM + PN and IM *vs.* ETAU: contrast mean difference = -0.43, $p < 0.001$; IM + PN *vs.* IM: contrast mean difference = -0.03, $p = 0.82$). Similarly, for opioid positive testing results over the 12 months, neither the combined IM + PN and IM *vs.* ETAU Group $\times$ Time [$F(3, 497) = 1.2$, $p = 0.32$] nor the IM + PN *vs.* IM Group $\times$ Time [$F(3, 497) = 1.7$, $p = 0.17$] were significant.

For all secondary analyses, significant findings for both the combined IM + PN and IM *vs.* ETAU and IM + PN *vs.* IM contrasts and the other effects were the same in the MITT as in the ITT analyses with the exception of self-reported days of illegal activity, which additionally showed a significant Gender effect ($p = 0.048$), with women reporting significantly more days of criminal activity, and a significant Gender $\times$ Time effect ($p = 0.036$), in which both women and men reported significantly decreasing their days of illegal activity from baseline to follow-up, although women had significantly more days of illegal activity than men only at 12-month follow-up ($p = 0.031$).

3.7. Completers analyses

Compared to non-completers, completers (participants who reported being in opioid agonist treatment at all time points) were significantly less likely to test opioid-positive during the follow-up period [EMMs = 0.45 and 0.68 for completers and non-completers, respectively; $p = 0.006$] and had significantly fewer days of heroin use (7.0 *vs.* 14.1 days; $p = 0.001$), cocaine use (6.0 *vs.* 11.3 days; $p = 0.008$), and crime (4.2 *vs.* 9.0 days; $p = 0.007$). A significant Completers $\times$ Time effect was found for past-30-day heroin use ($p = 0.007$). The mean number of days of use did not differ between groups at baseline, but was significantly fewer at all follow-up time points for completers than for non-completers.

4. Discussion

On an intention-to-treat basis, we found 80.3% of IM + PN and 57.1% of IM participants interviewed reported receiving their first methadone dose post-release at their assigned program. Sixty-seven percent of IM + PN participants were in any type of OUD treatment 30 days after release as compared to 57% of those treated with IM without a navigator and 24% of ETAU participants. The differences in treatment entry were more substantial than we had expected. Prior reports found that from 24% (Magura et al., 2009) to 56% (Tomasino et al., 2001) of jail inmates started on methadone maintenance “reported” to OUD treatment in the community, and 36% were in methadone treatment 30 days following release (Magura et al., 1993).

Although more participants receiving IM + PN relative to IM received their first dose of methadone in the community, there was considerable attrition in the IM + PN group, resulting in a non-significant difference in treatment status between the two groups by 1 month after release. It is likely that the patient navigator's efforts to help participants receive their first methadone dose were not sufficient enough to sustain their interest in attending community treatment on a daily basis. Although some patients entered other types of OUD treatment programs, by 12 months after release, the estimated marginal means for being in any kind of OUD treatment were only 0.40 for the IM + PN and 0.27 for the IM only groups. Over the same period, the ETAU group gradually entered various community treatment programs so that by 12 months there were no significant differences among the groups in terms of self-reported OUD treatment participation

As seen in the Consort Diagram (Fig. 1), at all follow-up points, there was a non-trivial percentage of participants who could not be located (*e.g.*, 15.3%, 12.7%, and 25.7% of IM + PN, IM, and ETAU groups at the 3-month follow-up, respectively). If we assume that—compared to those interviewed—more of the participants who were not located were not in treatment and that more had been using illicit opioids and cocaine, then the results presented for those interviewed would represent a best-case scenario.

Unexpectedly, as measured by opioid-positive urine tests on specimens obtained over the 12 months post-release, the two methadone groups did not differ significantly from the ETAU group, nor did IM significantly differ from IM + PN. While about 50%–70% of specimens obtained were positive for any illicit opioid, this level of positives contrasts the likely near 100% positive rate at the index arrest, suggesting there was some improvement from baseline to follow-up for the entire sample. The modest decline of opioid positive tests from baseline (assuming there would have been a positive test at baseline) was consistent with self-reported reduction in days of heroin use that showed significant reductions for the entire sample over time, but this ITT analysis did not show a significant difference by treatment group over time.

Participants reported significantly fewer days of cocaine use and crime over time, but the number of days reported for each was still quite high. Yet, there were no statistically significant improvements that could be ascribed to the assigned treatment groups. Women reported using heroin and cocaine on significantly more days than men. Cocaine use among individuals with OUD is a common and important problem. The number of self-reported days of cocaine use at baseline was significantly associated with the days of heroin use, cocaine positive urine tests, and the number of days of illegal activity over the 12-month follow-up period. Although contingency management focused on negative cocaine urine tests (Peirce et al., 2006) or work (Silverman et al., 2007) demonstrated efficacy among community treatment populations, whether it might be of some help in this population is uncertain.

Individuals released from jail are at heightened risk of overdose death (Binswanger et al., 2013; Merrall et al., 2010; Pizzicato et al., 2018). In a nationwide prospective study in England, Marsden and colleagues (2017) found that prisoners treated with doses of 20 mg of methadone or 2 mg of buprenorphine at release had an 85% reduction in overdose death

in the month following release compared to those receiving lower doses or no treatment. The mean methadone dose at release in our study was 41 mg, exceeding the threshold in the abovementioned study and likely affording some protection from overdose. It is noteworthy that none of the 5 participants who died of opioid overdose following release were enrolled in methadone treatment at the time and only 3 of the 48 (6.3%) non-fatal overdoses occurred during methadone treatment.

Currently, the literature on the impact of methadone treatment on incidence of crime does not yield a clear picture. Although early reports found a reduction in criminal behavior among participants in MMT (Dole et al., 1968; Hubbard et al., 1989), a more recent meta-analysis found no consistent effect of such treatment on crime (Mattick et al., 2009). However, nearly all the above-cited studies involved individuals seeking treatment in the community, rather than detainees with OUD who had not been in treatment. In a future report, we will present an analysis of the frequency and severity of arrest charges based on official records.

Five characteristics significantly distinguished the detainee participants in the present study from other participants we have studied in community-based MMT programs in Baltimore, and these characteristics tend to predict treatment outcome (Schwartz et al., 2019). About half of the participants recruited in the Detention Center were already on parole or probation; 63% had been arrested at least once in the year prior to the present index arrest; and they had already spent nearly one-third of their adult life incarcerated (an average of 71 months). These characteristics are associated with an increased hazard of continued involvement in the criminal justice system. Only about 37% had ever been in MMT prior to the index arrest despite relatively easy access to such treatment at little or no cost in Baltimore. Finally, the Detention Center sample had significantly more cocaine use than past community samples.

4.1. Limitations

The extent to which these study findings generalize to other cities or populations is not known. Findings also may not generalize to jail-based methadone programs able to provide higher average doses of methadone at release and/or counseling or other psychosocial interventions during detention. Findings may not generalize to other types of navigation such as navigation delivered by peers, for longer duration, or with financial or housing resources.

4.2. Concluding comments

The two groups assigned to initiate interim methadone treatment in jail had significantly higher rates of post-release treatment entry compared to the group that was not assigned to initiate MMT. However, methadone maintenance treatment discontinuation over the course of the 12-month follow-up attenuated the potential impact of treatment on participants' illicit drug use and criminal behavior. Given the lack of overdose deaths and the low rates of non-fatal overdose among study participants who remained enrolled in treatment in the community, the challenge remains on how best to sustain treatment retention following release from jail.

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Fig. 1.
Consort.

Table 1Participant characteristics at baseline ($N = 225$).

	Total sample ($N = 225$)	IM + PN ($n = 75$)	IM ($n = 74$)	ETAU ($n = 76$)	Test statistic (df)	p
Male, n (%)	181 (80.4)	60 (80.0)	60 (81.1)	61 (80.3)	$\chi^2(2) = 0.03$	0.99
Age, mean (SD)	38.3 (10.4)	39.6 (10.0)	37.3 (10.0)	37.9 (11.1)	$F(2, 222) = 0.99$	0.37
Hispanic, n (%)	6 (2.7)	3 (4.0)	0 (0.0)	3 (3.9)	$\chi^2(2) = 3.0$	0.22
Race, n (%)					$\chi^2(2) = 1.0$	0.60
Black/African American	139 (61.8)	51 (68.0)	45 (60.8)	43 (56.6)		
White	56 (24.9)	17 (22.7)	17 (23.0)	22 (28.9)		
Other race/ > 1 race	30 (13.3)	7 (9.3)	12 (16.2)	11 (14.5)		
Married, n (%)	43 (19.1)	13 (17.3)	14 (18.9)	16 (21.1)	$\chi^2(2) = 0.34$	0.84
Years of education, mean (SD)	11.3 (1.9)	11.4 (1.6)	11.0 (1.9)	11.6 (2.2)	$F(2, 222) = 2.1$	0.13
Employed past 30 days, n (%)	98 (43.6)	32 (42.7)	33 (44.6)	33 (43.4)	$\chi^2(2) = 0.06$	0.97
Number of days used cocaine past 30 days (baseline), mean (SD)	15.4 (13.6)	13.9 (13.4)	15.5 (13.8)	16.7 (13.7)	$F(2, 222) = 0.83$	0.44
Injected drugs past 6 months, n (%)	114 (50.7)	35 (46.7)	36 (48.6)	43 (56.6)	$\chi^2(2) = 1.7$	0.44
With prior methadone treatment admissions, n (%)	83 (36.9)	26 (34.7)	27 (36.5)	30 (39.5)	$\chi^2(2) = 0.38$	0.83
With any prior medication treatment for OUD, n (%)	121 (54.5)	40 (53.3)	41 (56.2)	40 (54.1)	$\chi^2(2) = 0.13$	0.94
On parole/probation, n (%)	109 (48.4)	31 (41.3)	36 (48.6)	42 (55.3)	$\chi^2(2) = 2.9$	0.23
Lifetime months of incarceration, mean (SD)	71.2 (75.1)	82.6 (85.3)	72.3 (72.0)	58.8 (65.6)	$F(2, 222) = 1.9$	0.15
Arrested during year prior to enrollment, n (%)	142 (63.1)	50 (66.7)	47 (63.5)	45 (59.2)	$\chi^2(2) = 0.91$	0.64

Notes: IM + PN = Interim Methadone + Patient Navigation; IM = Interim Methadone; ETAU = Enhanced Treatment as Usual. OUD = Opioid Use Disorder. Test statistic for "Race" was obtained by collapsing data into two categories: White ($n = 17$, $n = 17$, and $n = 22$ for IM + PN, IM, and ETAU, respectively) and African American/other ($n = 58$, $n = 57$, and $n = 54$ for IM + PN, IM, and ETAU, respectively). "Arrested during year prior to enrollment" does not include the index arrest. "Employed past 30 days" is defined as working 1 day in the past 30 days and includes legal and off-the-books employment. All variables were self-reported with the exception of "Arrested during year prior to enrollment" which was drawn from official arrest records. For variable "With any prior medication treatment for OUD," does not include medically supervised withdrawal. Data missing for 3 participants for this variable ($N = 222$).

Table 2

Self-reported opioid use disorder treatment entry for intention-to-treat sample at 30 days post-release ($N = 167$).

	Total sample ($N = 167$)	IM + PN ($n = 61$)	IM ($n = 56$)	ETAU ($n = 50$)
In any treatment 1 month after release, n (%)	85 (50.9)	41 (67.2)	32 (57.1)	12 (24.0)
Methadone Maintenance	69 (41.3)	38 (62.3)	30 (53.6)	1 (2.0)
Outpatient buprenorphine	8 (4.8)	0 (0.0)	1 (1.8)	7 (14.0)
Outpatient (counseling only)	7 (4.2)	3 (4.9)	1 (1.8)	3 (6.0)
Residential	1 (0.6)	0 (0.0)	0 (0.0)	1 (2.0)

Notes: Table includes self-report data from participants who were interviewed following release from detention to the community as well as those participants who were sentenced, transferred to prison from detention, and released subsequently to the community from prison. IM + PN = Interim Methadone + Patient Navigation; IM = Interim Methadone; ETAU = Enhanced Treatment as Usual. Assuming as a worst case scenario, that none of the participants who were not interviewed had been in treatment at 30 days post-release, the percentages of participants in treatment at 30 days post-release would be 57.8%, 45.1%, and 16.2% for the IM + PN, IM, and ETAU Groups, respectively.

Table 3

Test of effects for intention-to-treat sample's primary outcome whether in any treatment at 1-month follow-up ($N = 167$).

Effect	Test statistic	<i>p</i>
Group	$\chi^2(2) = 9.1$	0.01
Gender	$\chi^2(1) = 0.002$	0.97
Prior MMT admissions	$\chi^2(1) = 0.95$	0.33
Age	$\chi^2(1) = 6.1$	0.01
Baseline past-30-day number of days used cocaine	$\chi^2(1) = 0.22$	0.64
Group $\times$ Gender	$\chi^2(2) = 1.1$	0.59
Planned Contrast:		
Combined IM + PN and IM v. ETAU	$\chi^2(1) = 12.0$	0.001
Planned Contrast:		
IM + PN v. IM	$\chi^2(1) = 0.04$	0.84

Notes: Table includes data from participants released from detention to the community as well as those participants who were sentenced, transferred to prison from detention, and released subsequently to the community from prison. MMT = methadone maintenance treatment; IM + PN = Interim Methadone + Patient Navigation; IM = Interim Methadone; ETAU = Enhanced Treatment as Usual.

Table 4

Estimated marginal means (standard errors) for the Group $\times$ Time interaction effect for the primary outcome opioid urine testing results and secondary outcomes cocaine urine testing results, days of heroin use, cocaine use, and illegal activity, DSM-5 opioid and cocaine use disorder, and treatment status in the intention-to-treat sample ($N = 225$).

	Baseline	1-month	3-month	6-month	12-month
Opioid-positive tests					
IM + PN	–	0.70 (0.08)	0.59 (0.08)	0.49 (0.09)	0.46 (0.08)
IM	–	0.72 (0.09)	0.72 (0.09)	0.63 (0.10)	0.71 (0.09)
ETAU	–	0.66 (0.09)	0.73 (0.08)	0.71 (0.08)	0.59 (0.09)
Days of heroin use past 30 days					
IM + PN	27.74 (2.36)	8.66 (1.32)	13.46 (1.84)	13.56 (1.83)	12.35 (1.66)
IM	26.94 (2.38)	12.07 (1.72)	15.15 (1.84)	14.02 (1.90)	14.70 (1.82)
ETAU	26.98 (2.31)	14.88 (2.12)	16.18 (2.04)	15.42 (1.94)	15.35 (1.90)
DSM-5 opioid use disorder (OUD)					
IM + PN	–	–	0.66 (0.09)	0.51 (0.09)	0.54 (0.09)
IM	–	–	0.70 (0.08)	0.59 (0.09)	0.77 (0.11)
ETAU	–	–	0.76 (0.08)	0.77 (0.08)	0.59 (0.09)
Cocaine-positive tests					
IM + PN	–	0.49 (0.10)	0.64 (0.08)	0.55 (0.09)	0.61 (0.10)
IM	–	0.59 (0.10)	0.51 (0.10)	0.47 (0.10)	0.72 (0.10)
ETAU	–	0.55 (0.10)	0.55 (0.09)	0.53 (0.09)	0.56 (0.10)
Days of cocaine use past 30 days					
IM + PN	16.18 (2.05)	5.95 (1.29)	8.83 (1.71)	10.74 (1.86)	9.60 (1.70)
IM	18.72 (2.27)	9.05 (1.73)	11.32 (1.93)	13.57 (2.23)	14.46 (2.19)
ETAU	18.49 (2.25)	11.01 (2.10)	11.94 (2.14)	13.56 (2.04)	12.63 (2.01)
DSM-5 cocaine use disorder (CUD)					
IM + PN	0.76 (0.07)	–	0.20 (0.08)	0.22 (0.10)	0.32 (0.15)
IM	0.75 (0.10)	–	0.32 (0.11)	0.35 (0.12)	0.40 (0.20)
ETAU	0.68 (0.08)	–	0.32 (0.12)	0.36 (0.14)	0.30 (0.14)
Days of illegal activity past 30 days					
IM + PN	16.89 (1.85)	5.22 (1.29)	9.79 (1.81)	9.24 (1.88)	6.88 (1.54)

	Baseline	1-month	3-month	6-month	12-month
IM	17.58 (1.76)	8.18 (1.74)	9.35 (1.66)	9.74 (1.89)	9.97 (1.88)
ETAU	17.37 (1.76)	8.22 (2.15)	10.59 (2.15)	11.49 (1.99)	10.18 (1.99)
Enrollment in OUD treatment					
IM + PN	–	0.63 (0.08)	0.57 (0.08)	0.52 (0.09)	0.40 (0.09)
IM	–	0.56 (0.09)	0.47 (0.09)	0.52 (0.09)	0.27 (0.09)
ETAU	–	0.26 (0.08)	0.19 (0.07)	0.24 (0.07)	0.29 (0.08)

Notes: IM + PN = Interim Methadone + Patient Navigation; IM = Interim Methadone; ETAU = Enhanced Treatment as Usual. Analyses of opioid and cocaine urine testing results did not include baseline assessments because participants were not asked to provide a urine specimen while incarcerated. The number of participants included at each time point for outcome variables are as follows: opioid- and cocaine-positive tests: 1-month: $n = 145$, 3-month: $n = 131$, 6-month: $n = 140$, 12-month: $n = 141$; DSM-5 OUD: 3-month: $n = 155$, 6-month: $n = 161$, 12-month: $n = 162$ (baseline omitted because all participants met criteria for DSM-5 OUD at baseline; DSM-5 OUD not measured at 1 month); DSM-5 CUD: baseline: $n = 225$, 3-month: $n = 155$, 6-month: $n = 161$, 12-month: $n = 162$ (DSM-5 CUD not measured at 1 month); days of heroin and cocaine use past 30 days: baseline: $n = 225$, 1-month: $n = 160$, 3-month: $n = 155$, 6-month: $n = 161$, 12-month: $n = 162$; days of illegal activity past 30 days: baseline: $n = 224$, 1-month: $n = 160$, 3-month: $n = 155$, 6-month: $n = 161$, 12-month: $n = 162$; enrollment in OUD treatment: baseline: not measured, 1-month: $n = 167$, 3-month: $n = 173$, 6-month: $n = 178$, 12-month: $n = 180$. At each follow-up point, the following number of participants reported being enrolled in OUD treatment because they were continuing to receive methadone treatment in the Baltimore City Detention Center following re-arrest that occurred while in enrolled in community-based methadone treatment: 1 month: 4 IM + PN participants; 3 months: 3 IM + PN and 3 IM; 6 months: 2 IM + PN and 6 IM; and 12 months: 3 IM + PN and 2 IM.

Table 5

Source table for primary outcome opioid urine testing results and secondary outcomes cocaine urine testing results, days of heroin use, cocaine use, and illegal activity, and DSM-5 opioid and cocaine use disorder for intention-to-treat analyses ($N = 225$).

Source	Opioid urine testing test results			Days of heroin use past 30 days			DSM-5 opioid use disorder			Cocaine urine testing test results			Days of cocaine use past 30 days		
	F	df1, df2	p	F	df1, df2	p	F	df1, df2	p	F	df1, df2	p	F	df1, df2	p
Group	1.3	2, 536	0.28	2.0	2, 830	0.14	1.4	2, 457	0.24	0.04	2, 536	0.96	2.2	2, 831	0.11
Time	1.0	3, 536	0.39	36.9	4, 830	<0.001	0.94	2, 457	0.39	1.3	3, 536	0.28	15.0	4, 831	<0.001
Gender	0.14	1, 536	0.71	4.8	1, 830	0.03	0.57	1, 457	0.45	0.91	1, 536	0.34	28.1	1, 831	<0.001
Prior MMT admissions	0.10	1, 536	0.75	0.16	1, 830	0.69	0.07	1, 457	0.79	2.9	1, 536	0.09	0.42	1, 831	0.52
Age	2.8	1, 536	0.10	0.25	1, 830	0.62	8.7	1, 457	0.003	0.05	1,536	0.83	0.07	1, 831	0.80
Number of days used cocaine past 30 days (baseline)	0.004	1, 536	0.95	9.7	1, 830	0.002	1.5	1, 457	0.22	27.9	1, 536	<0.001	—	—	—
Group × Gender	1.6	2, 536	0.21	0.72	2, 830	0.49	0.08	2, 457	0.93	0.08	2, 536	0.92	1.2	2, 831	0.30
Group × Time	1.2	6, 536	0.33	1.1	8, 830	0.36	1.2	4, 457	0.31	1.3	6, 536	0.25	0.58	8,831	0.79
Planned Contrast:															
(Combined IM + PN and IM v. ETAU) × Time	1.2	3, 536	0.32	1.3	4, 830	0.28	2.2	2, 457	0.11	0.64	3, 536	0.59	0.67	4,831	0.61
Planned Contrast:															
(IM + PN v. IM) × Time	1.2	3, 536	0.32	0.95	4, 830	0.44	0.60	2, 457	0.55	2.1	3,536	0.11	0.53	4, 831	0.72
Time × Gender	1.1	3, 536	0.33	4.3	4, 830	0.002	0.52	2, 457	0.60	1.2	3, 536	0.31	3.0	4, 831	0.02
Group × Gender × Time	—	—	—	0.69	8, 830	0.70	1.3	4, 457	0.26	—	—	—	0.67	8,831	0.72
Source	DSM-5 cocaine use disorder			Days of illegal activity past 30 days			Enrollment in OUD treatment								
	F	df1, df2	p	F	df1, df2	p	F	df1, df2	p	F	df1, df2	p			
Group	0.37	2,676	0.69	1.0	2,829	0.37	5.4	2, 671	0.005						
Time	10.5	3,676	<0.001	16.3	4,829	<0.001	2.7	3, 671	0.046						
Gender	0.59	1,676	0.44	2.8	1,829	0.09	0.30	1, 671	0.59						
Prior MMT admissions	1.2	1, 676	0.28	0.68	1, 829	0.41	0.33	1, 671	0.57						
Age	0.29	1, 676	0.59	22.7	1, 829	<0.001	19.2	1, 671	<0.001						
Days used cocaine past 30 days (baseline)	143.5	1, 676	<0.001	13.9	1, 829	<0.001	1.3	1, 671	0.26						

Source	DSM-5 cocaine use disorder			Days of illegal activity past 30 days			Enrollment in OUD treatment		
	<i>F</i>	<i>df1, df2</i>	<i>p</i>	<i>F</i>	<i>df1, df2</i>	<i>p</i>	<i>F</i>	<i>df1, df2</i>	<i>p</i>
Group × Gender	0.10	2, 676	0.90	1.5	2, 829	0.22	0.73	2, 671	0.48
Group × Time	0.38	6, 676	0.90	0.61	8, 829	0.77	1.2	6, 671	0.30
Planned Contrast:									
(Combined IM + PN and IM v. ETAU) × Time	0.46	3, 676	0.71	0.31	4, 829	0.87	2.1	3, 671	0.10
Planned Contrast:									
(IM + PN v. IM) × Time	0.25	3, 676	0.86	0.97	4, 829	0.42	0.43	3, 671	0.74
Time × Gender	1.0	3, 676	0.39	2.1	4, 829	0.08	0.47	3, 671	0.70
Group × Gender × Time	1.0	6, 676	0.41	1.6	8, 829	0.12	1.2	6, 671	0.31

Notes: IM+PN=Interim Methadone + Patient Navigation; IM = Interim Methadone; ETAU = Enhanced Treatment as Usual. OUD = opioid use disorder. *df1* and *df2* are the degrees of freedom for the respective *F* test statistic. Analyses of opioid and cocaine urine testing results did not include baseline assessments because participants were not asked to provide urine specimens while incarcerated. DSM-5 opioid use disorder was not analyzed at baseline because meeting its criteria was one of the inclusion criteria. Control variable, "Number of days used cocaine past 30 days (baseline)" was not included in analysis for outcome "Days of cocaine use past 30 days" because baseline cocaine use is included as part of this outcome. The Group × Gender × Time interaction effect was excluded from the analyses of opioid and cocaine testing results due to an empty cell.