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A randomized clinical trial of buprenorphine for prisoners: Findings at 12-months post-release

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Abstract

Background—This study examined whether starting buprenorphine treatment prior to prison and after release from prison would be associated with better drug treatment outcomes and whether males and females responded differently to the combination of in-prison treatment and post-release service setting.

Methods—Study design was a 2 (In-Prison Treatment Condition: Buprenorphine Treatment Vs. Counseling Only) X 2 [Post-Release Service Setting Condition: Opioid Treatment Program (OTP) Vs. Community Health Center (CHC)] X 2 (Gender) factorial design. The trial was conducted between September 2008 and July 2012. Follow-up assessments were completed in 2014.

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Contributors

All authors contributed to and approved the final manuscript. The manuscript is the work of the authors alone. Authors Kinlock, Gordon, Schwartz, and O'Grady designed the study and wrote the protocol. All authors contributed to summaries of previous work. Author Gordon wrote the first draft of the manuscript. Authors Gordon, Schwartz, and O'Grady wrote the first draft of the tables and figures. Author O'Grady made the primary contribution to the statistical analyses.

Conflict of Interest

This study was supported by an unrestricted, unsolicited investigator initiated request from Reckitt Benckiser Pharmaceuticals, Inc. (provided study drug only) who had no role in study design; collection, analysis and interpretation of data; in the writing of the manuscript; or in the decision to submit the manuscript for publication. The authors alone are responsible for the content and writing of this manuscript. Drs. Gordon, Kinlock, and Fitzgerald received funding from Alkermes on a prior study. Dr. Schwartz did a one-time consultation for Reckitt-Benckiser on behalf of his employer (the Friends Research Institute). Dr. O'Grady has in the past received funding for his time from Reckitt-Benckiser. Dr. Vocci has consulted with and received other funding (meals, travel expenses) from the following companies: Braeburn Pharmaceuticals, Demerx, Indivior, Pinney Associates. He has received travel and meal expenses from Intratab Labs Inc., and received consulting fees from Alkermes and Usona Institute. All of Dr. Vocci's consulting fees go to his employer, Friends Research Institute, Inc.

Participants were recruited from two Baltimore prerelease prisons (one for men and one for women). Adult pre-release prisoners who were heroin-dependent during the year prior to incarceration were eligible. Post-release assessments were conducted at 1, 3, 6, and 12-month following prison release.

Results—Participants (*N*=211) in the in-prison treatment condition effect had a higher mean number of days of community buprenorphine treatment compared to the condition in which participants initiated medication after release (P=.005). However, there were no statistically significant hypothesized effects for the in-prison treatment condition in terms of: days of heroin use and crime, and opioid and cocaine positive urine screening test results (all Ps>.14) and no statistically significant hypothesized gender effects (all Ps>.18).

Conclusions—Although initiating buprenorphine treatment in prison compared to after-release was associated with more days receiving buprenorphine treatment in the designated community treatment program during the 12-months post-release assessment, it was not associated with superior outcomes in terms of heroin and cocaine use and criminal behavior.

Keywords

buprenorphine; prisoners; heroin addiction; opioid substitution therapy

1. Introduction

Inmates in the United States (US), Australia, and in many European and Asian countries have substantially higher rates of heroin addiction than the general population (Dolan et al., 2007; Fazel et al., 2006; Kanato, 2008; Kastelic et al., 2008). Some heroin-addicted inmates continue use during incarceration while others who became abstinent during incarceration, relapse quickly - typically within one month after release (Dolan et al., 2007; Kinlock et al., 2011; Strang et al., 2006). Relapse after release poses a risk of HIV or hepatitis infection (Dolan et al., 2007; Inciardi, 2008; Kanato, 2008), overdose death (Binswanger et al., 2012; Farrell and Marsden, 2008; Krinsky et al., 2009; Lim et al., 2012; Merral et al., 2010; Stoove and Kinner, 2014), return to criminal activity (Hough, 2002; Kinlock et al., 2003; Inciardi, 2008), and re-incarceration (Dolan et al., 2005; Metz et al., 2010).

Despite the high rate of heroin addiction among inmates and the public health and safety risk engendered by their release from custody, many inmates remain untreated while incarcerated and do not receive treatment upon release (Dolan et al., 2007; Gordon et al., 2014; Kastelic et al., 2008; Lee et al., 2015; Stover and Michels, 2010; Taxman et al., 2007). Therefore, there is a need to adapt and evaluate treatments for opioid use disorder that have proven effectiveness within community settings for prison settings (Chandler et al., 2009; Degenhardt et al., 2014; Dolan et al., 2007; Kinlock et al., 2011).

There are three medications that are approved by the US Food and Drug Administration for the treatment of opioid dependence, including the opioid antagonist naltrexone, the opioid agonist methadone, and the opioid partial agonist buprenorphine. Extended release naltrexone has promise for use just prior to release from incarceration because it affords about a month of protection from opioid overdose and its use has been shown feasible in a

pilot study within a New York City jail (Lee et al., 2015) and with criminal justice populations in the community (Lee et al., 2016). Methadone has been examined in randomized clinical trials within prisons in which inmates were actively using opioids during incarceration (Dolan et al., 2005), and after they had been opioid abstinent for varying periods of time (Dole et al., 1969; McKenzie et al., 2012; Gordon et al., 2008; Kinlock et al., 2007; Kinlock et al., 2009; Kinlock et al., 2008). These studies of methadone overall show that starting methadone prior to release from prison increases the likelihood of treatment entry and reduces the likelihood of illicit opioid use after release.

Despite findings regarding the benefits of providing methadone prior to release, most corrections agencies in the US do not offer methadone maintenance treatment (MMT) in their facilities (Bruce and Schleifer, 2008; Dolan et al., 2007; Friedman et al., 2012; Gordon et al., 2014; Lee et al., 2015; Magura et al., 2009; Nunn et al., 2009), due to their preference for non-medication approaches, lack of focus on rehabilitation, security concerns about medication diversion, lack of knowledge about the effectiveness of methadone treatment, and stigma (McKenzie et al., 2009; Nunn et al., 2009). Buprenorphine is an alternative to methadone for use in correctional settings (Lee et al., 2015; Magura et al., 2009) and it is widely available in prisons in France (Favrod-Coune et al., 2013; Marzo et al., 2009). Buprenorphine has a number of potential advantages over methadone for use in correctional settings. The former has a lower risk of opioid overdose; less associated stigma; and fewer regulations in the US, which permit its use outside of specially regulated opioid treatment programs (OTPs; Albizu-Garcia et al., 2007; Dasgupta et al., 2010; Magura et al., 2009). This latter fact affords the possibility that buprenorphine patients released from correctional institutions could seek continuing care either in an OTP, a physician’s office or health clinic, or an outpatient substance abuse treatment program, which have fewer regulatory restrictions than an OTP. Outpatient substance abuse treatment programs can be freestanding or embedded within a community health center. Receiving buprenorphine in a health care setting might be advantageous, as it may have less stigma associated with it than an OTP and could provide other needed health and mental health services, which might be particularly beneficial for women (O’Connor et al., 1998; Samet et al., 2001; Sullivan et al., 2005). Moreover, among adults with heroin use disorder, women may have greater need for health and mental health services (Chatham et al., 1999, Rowan-Szal et al., 2000), which are more likely to be provided in a CHC than in an OTP. Thus, receiving one-stop services at the CHC compared to an OTP may increase treatment retention among women compared to men.

Buprenorphine, unlike methadone, can be administered on alternate days [Amass et al., 2000; Center for Substance Abuse Treatment (CSAT), 2004], a feature that would make its use more efficient in correctional settings than methadone (Magura et al., 2009). Observational studies of buprenorphine in correctional settings in Puerto Rico (Garcia et al., 2007) and Rhode Island (Zaller et al., 2013) found that it was feasible to administer and that it facilitated community-based treatment entry. An RCT comparing methadone to buprenorphine treatment conducted in a New York City jail among newly-arrested inmates in opioid withdrawal found that while treatment completion rates in jail were similar, buprenorphine patients were significantly more likely to enter community-based treatment despite being significantly more likely than methadone patients to be terminated from treatment in jail for attempted medication diversion (Magura et al., 2009). However, at a

three-month post-release follow-up, there were no group differences in terms of self-reported relapse to illicit opioid use, severity of criminal behavior, or re-arrest.

1.1 The present study

Our group previously reported on an RCT of buprenorphine treatment among prerelease prisoners who had been incarcerated for relatively longer periods of time (Mean days of incarceration=568.7, *SD*=956.9) and who were mostly opioid-abstinent at the time of study enrollment (Gordon et al., 2014; NCT00574067)). Adult men and women prisoners with pre-incarceration histories of opioid dependence who were within three to nine months of release were randomly assigned within gender either to begin buprenorphine treatment in prison or after release from prison; and, after release from prison, either to receive buprenorphine treatment in the community at either an OTP or an outpatient substance abuse treatment program within a Community Health Center (CHC).

The present paper reports the longer-term outcomes from the above-mentioned RCT over a 12-month period post-prison release. We examine two specific hypotheses:

(1) The condition that initiated buprenorphine in prison would have more favorable outcomes than would the condition that initiated buprenorphine in the community; and

(2) Males and females would respond differentially to the combination of In-Prison Treatment (In-Prison Vs. Out-Of-Prison Buprenorphine Treatment) and Post-Release Service Setting (OTP vs. CHC)

2. Methods

2.1. Overview

Study description and methods were detailed previously (Gordon et al., 2014; Gordon et al., 2013; Kinlock et al., 2010; Vocci et al., 2015). Adult men and women in prison in Baltimore who met eligibility criteria described below and provided informed consent for participation were randomly assigned within gender to begin buprenorphine either (1) in prison and continue care in an OTP or in (2) an outpatient substance abuse program within a CHC; or to begin buprenorphine after release from prison (3) in an OTP or (4) in the CHC. Thus, the basic design of the study was a 2 (In-Prison Treatment Condition: Buprenorphine Treatment Vs. Counseling Only) x 2 (Post-Release Service Setting: OTP vs. CHC) factorial. All participants were expected to complete an individual counseling assessment and to attend 12 weekly sessions of group-based substance abuse counseling prior to release. Just prior to discharge, an individual discharge planning session with the study counselor was also available. The study was approved by the Friends Research Institute's Institutional Review Board, by the Maryland Department of Public Safety and Correctional Services' (DPSCS) research committee, and by the US Office of Human Research Protection.

2.2. Inclusion/Exclusion Criteria

In order to be eligible for study participation, consenting prisoners had to: be at least 18 years of age; be within 3 to 9 months prior to scheduled release; have met DSM-IV criteria

for opioid dependence in the year prior to incarceration; be considered by the study physician to be medically suitable for buprenorphine; and plan to live in Baltimore after release. Exclusion criteria were: liver or kidney failure; history of psychosis; having a pending parole hearing; or, un-adjudicated charges.

2.3. Recruitment and randomization

Research assistants (RA) held group information sessions about the study to recruit prisoners for screening which were conducted individually in a private space. Following informed consent, the RA administered the assessment battery described below and scheduled the prisoner for a history and physical exam by the study physician. Individuals who met eligibility criteria were randomly assigned to either buprenorphine and counseling in prison continued (1) at an OTP upon release or (2) at a CHC upon release; counseling only in prison with buprenorphine and counseling (3) at an OTP upon release or (4) at a CHC upon release by the RA who opened a sealed, opaque envelope that was numbered by the project manager following a sequence that was generated by a random permutation computer program.

2.4. Treatment in Prison

All participants had a counseling visit for an individual psychosocial assessment after random assignment and an individual discharge planning visit in which participants were reminded that they had up to 10 days to report to their community treatment program for continuing care. In addition, participants were expected to attend 12 weekly group-based substance abuse counseling sessions that were largely psychoeducational in nature. Buprenorphine treatment in prison was provided by the medical and nursing staff from a community-based OTP, distinct from the OTP receiving participants post-release in order to reduce the likelihood of biasing community treatment entry rates in favor of the OTP compared to the CHC arms. Daily dosing of buprenorphine/naloxone was directly administered by nursing with a goal of starting at 1 mg daily and increased slowly (initially by 1mg per week until reaching 4 mg per day, and subsequently by 2 mg per week until reaching 8 mg). This slow induction was used because most participants were not opioid tolerant at enrollment. After a period of stabilization at 8 mg, participants were to begin 16 mg on alternating days and eventually to reach a three-day per week dosing schedule. For a more complete description of dosing, see Vocci et al. (2015).

2.5. Assessments

Participants were assessed five times during the course of the study: at baseline (study entry) and at 1, 3, 6, and 12 months post-release. Assessments included the Addiction Severity Index (ASI; McLellan et al., 1992) for past-30-day opioid and cocaine use and criminal activity and a questionnaire addressing substance abuse treatment received and days of incarceration (Hanlon et al., 1990; Nurco, 1998). Self-reported heroin use, cocaine use, and criminal activity were collected at baseline for the period of 30 days prior to the index incarceration, which, for the majority of participants, was 2–4 years prior to the baseline assessment. The baseline data were gathered for descriptive purposes only and, therefore, were not included in the statistical analyses. Opioid and cocaine urine screening was conducted by a certified laboratory using Enzyme Multiplied Immunoassay Technique

(EMIT) at all follow-up interviews, but not at baseline. Participants were paid $20 for all completed assessments except the baseline, for which there was no payment.

2.6. Outcome measures

The primary outcome measure was the number of self-reported days of heroin use in the 30 days prior to each follow-up assessment. Secondary outcome measures included opioid (methadone or buprenorphine that was not prescribed for treatment, i.e., oxycodone, codeine), cocaine-positive urine screens at each follow-up point, treatment retention, defined as the number of days in the designated substance abuse treatment program during the 12-month follow-up period, and self-reported cocaine use and illegal activity (excluding illicit substance use and/or possession) in the 30 days prior to each follow-up interval. It should be noted that if participants tested positive for methadone or buprenorphine and were not in a treatment program, results were counted as positive.

Data on substance abuse treatment status were obtained from treatment program records and participant self-report. Data on self-reported heroin use, cocaine use, and criminal activity, were obtained from the ASI. The continuous outcome measures were adjusted for days at risk in the community based on the percentage of days that participants were in the community and, therefore, had full opportunity to use illicit substances and commit crime.

2.7. Hypotheses

Regarding all outcomes, there were two hypotheses of interest:

(1) The condition that initiated buprenorphine in prison would have more favorable outcomes than would the condition that initiated buprenorphine in the community. The test of this hypothesis would be the main effect test of the In-Prison Treatment Condition X Time interaction for treatment retention, measured only at study conclusion and all other outcomes measured repeatedly.

(2) Males and females would respond differentially to the combination of in-prison treatment and post-release service setting. For those participants who were assigned to receive buprenorphine in prison, males would respond more favorably than females to a post-release OTP setting while females would respond more favorably than males to a post-release CHC setting.

In contrast, it was expected that participants who received counseling only in prison, regardless of gender and post-release service setting, would have comparable and uniformly poorer outcomes than participants who received buprenorphine in prison. The test of this hypothesis would be the In-prison Gender X In-prison Treatment Condition X Post-release Service Setting X Time interaction for all outcomes except treatment retention, and the Gender X In-prison Treatment Condition X Post-release Service Setting for treatment retention.

2.8. Statistical analysis

The statistical model was a 2 (In-Prison Treatment Condition: Buprenorphine Treatment Vs. Counseling Only) X 2 Post-release Service Setting (OTP vs. CHC) X 2 (Gender) factorial design. Time was included in the model as an additional effect for the outcomes that were

measured repeatedly. A generalized linear mixed model (McCullagh and Nelder, 1989) was used for the analysis of all outcomes, with the assumption of an underlying Poisson distribution for the count variables (i.e., days in treatment, days used heroin, cocaine, and criminal activity days) and a binomial distribution for the dichotomous variables (i.e., in treatment, urine drug screen for heroin and cocaine). Interpretation focused on the estimated marginal means associated with significant effects. In the case of count variables, these means were back-transformed from the Poisson estimates to the metric of the respective observed variable, while for the dichotomous variables, the means represent posterior probability estimates.

2.8.1. Study Power—The study was originally designed to recruit 320 participants. Power was estimated using Stroup's (Littell et al., 2006; Stroup 1999) four-step procedure, while minimum effect sizes were calculated using Cohen's set correlation method (Cohen 1988). The resulting power values ($1 - \beta$) for the effects of interest varied between .80 and .97 in the simulations. While every effort was made to ensure that the projected number of participants was obtained, enrollment yielded a total of 211 participants, 109 less than anticipated. Power calculation for this sample size still yielded an effect size f^2 of .04 for the primary outcome, which falls in the "small" range, using Cohen's (1988) terminology, where an f^2 of .02 is considered a small effect.

3. Results

Study screening, enrollment, intervention, and follow-up flow are shown in the Consolidated Standards of Reporting Trials (CONSORT) diagram (Figure 1).

3.1. Post-release follow-up

Post release treatment retention and self-report data were gathered for the 211 participants at the following time periods: one-month (204, 96.7%), three-month (204, 96.7%), six-month (176, 86.3%), and twelve-month (150, 71.1%). Urine specimens were collected for 137 (64.9%) at one-month, 147 (69.7%) at three-month, 140 (66.4%) at six-month, and 124 (58.8%) at twelve-month visits (see footnote of Table 3 for an explanation of the differences in sample size between self-report and urine drug screening).

3.2. Participant characteristics

Selected background characteristics of the 211 study participants by treatment condition are shown in Table 1. Most were African American, between 35 and 45 years of age, had not completed high school and had had at least six previous incarcerations. Participants, on average, began heroin use in their late teens, generally 4–5 years after the onset of criminal activity. In the 30 days prior to their current incarceration, participants reported, on average, using heroin and committing crime nearly every day. While at least two-thirds of members of each study condition reported previous substance abuse treatment, approximately 20–25% reported previous methadone maintenance treatment and 30% previous buprenorphine treatment.

Using χ^2 tests of independence for categorical variables and *t* tests for continuous variables, there were no statistical significant differences (all *P*s>.05) between the four treatment conditions on the variables reported in Table 1. Participants were also compared by gender on the variables reported in Table 1. Women were significantly (*P*<.05) more likely to have undergone prior substance abuse treatment than men [$\chi^2(1)=10.7$; 95 % vs. 76%] and to have received buprenorphine treatment [$\chi^2(1) =12.5$; 28.6 vs. 9.5%]. Men had significantly (*P*s<.05) younger mean ages at first crime [*t*(208)=2.3; 13.1 vs. 15.2], at first use of heroin [*t* (209) = 2.3; 18.7 vs. 20.7], at first arrest [*t*(209)=4.3; 17.1 vs. 22.6], and at first incarceration [*t*(208) = 4.4; 19.6 vs. 24.3]. Women were also significantly younger than men at baseline assessment [*t* (209) = −2.3, *P*<.05; Mean ages = 37.0 vs. 40.0, respectively]. Finally, men and women differed significantly [$\chi^2(2)= 9.7$; *P*<.05] with regard to ethnicity, as 56% of the women were African American and 40% were white; for men, 76% were African American and 20% were white.

3.3. Hypothesis 1

There were no significant differences in the primary outcome of self-reported heroin use days between conditions that started buprenorphine in-prison vs. after release. There was an In-prison Treatment Condition main effect for treatment retention such that the initiating buprenorphine in the prison condition had a higher mean number of days retained in treatment than did the condition initiating medication after release [65.9 (*SE*=12.2) days *v.* 21.8 (*SE*=7.6) days, respectively*; P*=.005], and there was a significant In-prison Treatment Condition X Time interaction effect for self-reported cocaine use, with both conditions showing corresponding rises from one-month assessments through six-month assessments, with a decline moving from 6- to 12-month assessment, possibly attributable to missing data due to re-incarceration. No other hypothesized effect was significant, including for self-reported days of crime, and opioid and cocaine positive drug screens.

Figures 2 and 3 contain estimated marginal means and standard errors for opioid use days and opioid-positive urine screening results, for buprenorphine in prison versus buprenorphine in the community conditions. Finally, we examined opioid-positive screening test results for the In-Prison Buprenorphine Condition X Time interaction effect in the subsample of participants who entered outpatient buprenorphine treatment in the community in order to determine if those who entered treatment were more likely to have negative urine opioid results compared to those who did not enter treatment. We found no significant differences [at 1, 3, 6 and 12 months, respectively: Buprenorphine In Prison Condition [M=.12 (*SE*=.06), M=.11 (*SE*=.05), M=.12 (*SE*=.06), and M=.19 (*SE*=.08)]; Buprenorphine After Release Condition [M=.22 (*SE*=.09), M=.33 (*SE*=.09), M=.46 (*SE*=.14), and M=.33 (*SE*=.12), P>.05].

3.4. Hypothesis 2

All hypothesized effects regarding gender were statistically nonsignificant.

3.5. Time Effect

The time main effect was statistically significant for past-30 day heroin and cocaine use and past-30-day number of crime days. For past-30-day heroin and cocaine use, post hoc

pairwise simple mean comparisons indicated that the respective 1-month follow-up means were significantly lower than the 3-, 6-, and 12-month means, the respective 3-month means were significantly lower than the 6-month means, and the respective 6-month means were significantly higher than the 12-month means (all *P*s<.04). For crime days, there were three differences among the time periods that were statistically significant: (1) The 1-month follow-up mean was significantly lower than the 6-month follow-up mean (*P*<.001); (2) The 3-month follow-up mean was significantly lower than the 6-month follow-up mean (*P*=.001); and (3), The 6-month follow-up mean was significantly higher than 12-month follow-up mean (*P*=.007).

3.6. Other Effects

There were four other statistically significant effects. The gender main effect was statistically significant for opioid urine screening, with females less likely to test positive than males [*M*s=.19 (*SE*=.04) *v.* 34 (*SE*=.04)]. There was a statistically significant Gender X Time interaction effect for past-30-day heroin use, with the escalating means moving from 1-month to 3-month to 6-month post-baseline assessment showing no significant differences between females and males, while females show markedly less heroin use days than males at 12-months [1-, 3-, 6-, and 12-month *M*s= 3.7 (1.0), 5.9 (1.4), 8.3 (1.7), and 3.0 (.9) for females; 4.3 (.7), 5.8 (.8), 7.3 (1.1), and 7.7 (1.2) for males, respectively]. The Post-release Service Setting X Time interaction was statistically significant for opioid positive urine screen, with the OTP 1-month and CHC 3-month means significantly lower than the OTP 3-month mean [1-, 3-, 6-, and 12-month *M*s= .18 (.05), .22 (.06), .38 (.07), and .31 (.06) for OTP; .26 (.05), .30 (.07), .18 (.05), and .27 (.06) for CHC, respectively]. There was a statistically significant In-prison Treatment Condition X Post-release Service Setting interaction effect for past-30-day cocaine use with means for the in-prison buprenorphine condition lower in the OTP condition than the CHC condition [Ms=2.1 (SE=.61) *v.* 3.6 (SE=.96)] with the reverse the case for the in-prison counseling condition [Ms=3.8 (SE=1.00) *v.* 1.9 (SE=.69)]. However, pairwise comparisons among the means were nonsignificant.

3.7. Serious Adverse Events (SAEs)

There were a total of 42 hospitalizations (buprenorphine in prison, *n*=21 vs. counseling in prison, *n*=21), all of which were reviewed by the IRB and the study's DSMB and were determined to be not-study related. There were no deaths.

4. Discussion

This study was the first randomized clinical trial conducted in a US prison of buprenorphine treatment for pre-release prisoners. Unlike in France, Switzerland, and elsewhere (Favrod-Coune et al., 2013; Marzo et al., 2009), buprenorphine treatment is rarely available to US prisoners (Nunn et al., 2009). Given the high relapse rates to illicit opioid use upon release from prison (Binswanger et al., 2011), we sought to determine whether making buprenorphine treatment available prior to release compared to after release would afford superior outcomes over a 12-month community follow-up. This question is of some importance given the effectiveness of buprenorphine treatment in reducing heroin use in the

community (Mattick, et al., 2008) and the many barriers to implementing opioid agonist treatment during incarceration in the US (Gordon, Kinlock, Miller, 2011; Zaller et al., 2013).

With regard to hypothesis 1, the in-prison buprenorphine condition had more than triple the estimated mean number of days in treatment (65.9) compared to condition that was assigned to begin buprenorphine in the community (21.8). This finding may have been due in part to the significantly greater rates of treatment entry post-release among those inmates who started medication in prison (47.5%) compared to after release (33.7%) as reported in our short-term outcome paper (Gordon et al., 2014). These findings that starting medication prior to release leads to significantly greater treatment entry and retention were also found in our study of methadone treatment for male prisoners conducted in the same prison six years prior. In that study, we found that the group assigned to start methadone in prison vs. after release had significantly higher post-release treatment entry rates (69% *v.* 50%; Kinlock et al., 2007) and number of days in community treatment over 12 months (166 vs. 91.3) (Kinlock et al., 2009). It should be noted that the rates of treatment entry and number of days in treatment in the methadone study exceeded those of the buprenorphine study, thus, methadone may be more effective at retaining prisoners in treatment after release than buprenorphine. However, only a head-to-head comparison would be able to answer this question with certainty.

Hypothesis 2 regarding an interaction of gender with the In-Prison Treatment and Post-release Service Setting Conditions was not supported, as this interaction effect was not statistically significant in any analysis. However, there was a statistically significant gender main effect such that women were less likely to test positive for opioids in the community as well as a statistically significant gender by time effect for self-reported heroin use days favoring women. Thus, it would appear that women may have responded more positively to buprenorphine, although there are other potential explanations for these findings, including self-report bias.

Although retention in treatment is an important surrogate outcome for opioid agonist treatment and longer retention in buprenorphine treatment is associated with superior treatment outcomes (Curcio et al., 2011; Parran et al., 2010; Soeffing et al., 2009), the ultimate test of the efficacy of such treatment is the suppression of illicit opioid use. Thus, it should be noted that there were no differences between In-prison Treatment or Post-release Treatment Conditions in terms of self-reported opioid use or opioid-positive drug tests. This is in contrast to the above-mentioned study of methadone treatment which found that the Condition that started methadone in prison compared to after release had significantly lower rates of opioid-positive urine tests at 12 months post-release (25% v. 48.7%; Kinlock et al., 2009). However these findings should be interpreted with caution because there was a considerable number of missing urine specimens in both studies and we are not aware of similar studies reporting 12-month outcomes, which would confirm these findings.

Cocaine use frequently accompanies illicit opioid use. In the present study, there were three significant effects for past-30-day cocaine use but no differences with regard to urine cocaine screening test results. In the above-mentioned methadone study, at the 12-month

follow-up, the condition that started methadone in prison compared to after release had significantly lower rates of cocaine positive urine tests (44% v. 66%).

One of the potential benefits of starting buprenorphine in prison would be to reduce criminal behavior upon release. However, the only significant effect for number of days of criminal behavior in the present study was the Time main effect. Notably, there were also no significant differences at 12-months post-release between the methadone condition and the no medication condition in days of self-reported criminal behavior in our previous methadone study (Kinlock et al., 2009). Furthermore, this finding is consistent with results reported in a longitudinal study at Rikers Island several decades ago (Magura et al., 1993) that found no significant differences between participants in that jail's methadone program and a comparison group of untreated inmates with regard to the mean number of days engaged in property crime at follow-up. Criminal behavior is multi-determined and in low SES populations, such as the participants in the present study, not all criminal behavior is drug-related and hence may not be amenable to reduction resulting from drug treatment participation.

Prisoners with histories of opioid use disorder are at heightened risk of overdose after release to the community (Binswanger et al., 2011). In the present study, there were no overdose deaths. In contrast, in our methadone study, there were 4 overdose deaths during the 12-month release period – all of which were in the condition in which participants were provided counseling but no medication in prison and given a passive referral to drug abuse treatment in the community (Kinlock et al., 2009). Given the low base rate of opioid overdose, it is difficult to draw conclusions from these findings, although they are suggestive of the benefit of making specific links to opioid agonist treatment either in or out of prison.

Given the lack of significant differences (except for treatment exposure) between starting buprenorphine in prison vs. after release and the logistical and cost challenges to initiating it in prison, a reasonable alternative to starting medication in prison might be to provide an effective linkage to treatment upon release. Furthermore, it is important to note that the current study lacked a true control group (no medication arm). As indicated by previous medication studies (Gordon et al., 2008; Kinlock et al., 2009), one could hypothesize that a no medication arm would have had significantly higher rates of opioid use. There is much room for improvement in terms of community treatment retention and outcomes for this challenging population and research attention should be turned to this issue.

There are several limitations to this study. We were only able to obtain urine samples on 64% all of the 211 participants, mainly due to re-incarceration, or to an interview conducted by timeline follow-up after its due date. While treatment retention data were obtained for nearly the entire sample (through examination of the program records), because an increasing number of participants were not available for interview during incarceration, the self-report findings may have been influenced by differential attrition across the follow-up times. The sample involved fewer women than anticipated because the originally used women's prison closed for almost one-year and fewer women are incarcerated than men, which might limit generalizability. This study was conducted in a single city with a predominantly African American population and, therefore, the extent to which it

generalizes to other locales and populations is not known. Moreover, we did not reach our intended recruitment sample size. However, even with the reduced sample size it had power to detect small-to-medium effect sizes. Furthermore, much caution should be used in generalizing findings to countries in which universal access to community drug abuse treatment is afforded. Despite these limitations, results regarding treatment retention suggest that this approach may have promise if treatment entry and retention rates could be further improved.

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Highlights

- Many inmates addicted to heroin remain untreated while incarcerated.
- Buprenorphine in-prison was associated with greater community treatment postrelease.
- In-prison Treatment group had a higher mean number of days of post-release treatment.
- Groups did not differ on drug use or criminal behavior outcomes.

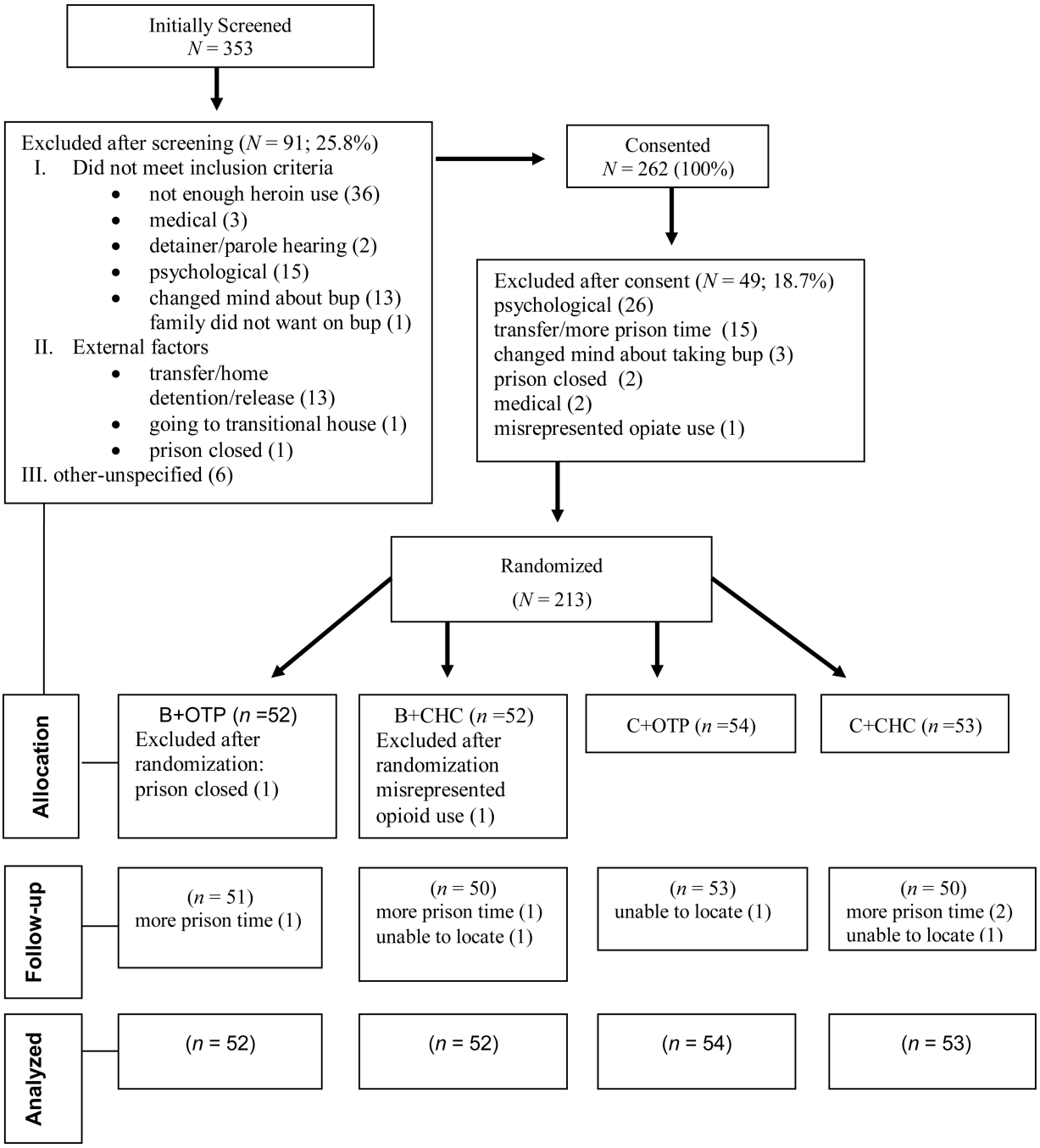

Figure 1. Consort Diagram

B+OTP: Buprenorphine in prison and continued at an Opioid Treatment Program (OTP)

B+CHC: Buprenorphine in prison and continued an a Community Health Center (CHC)

C+OTP: Counseling only in prison and initiation of buprenorphine at an OT

C+CHC: Counseling only in prison and initiation of buprenorphine at a CHC

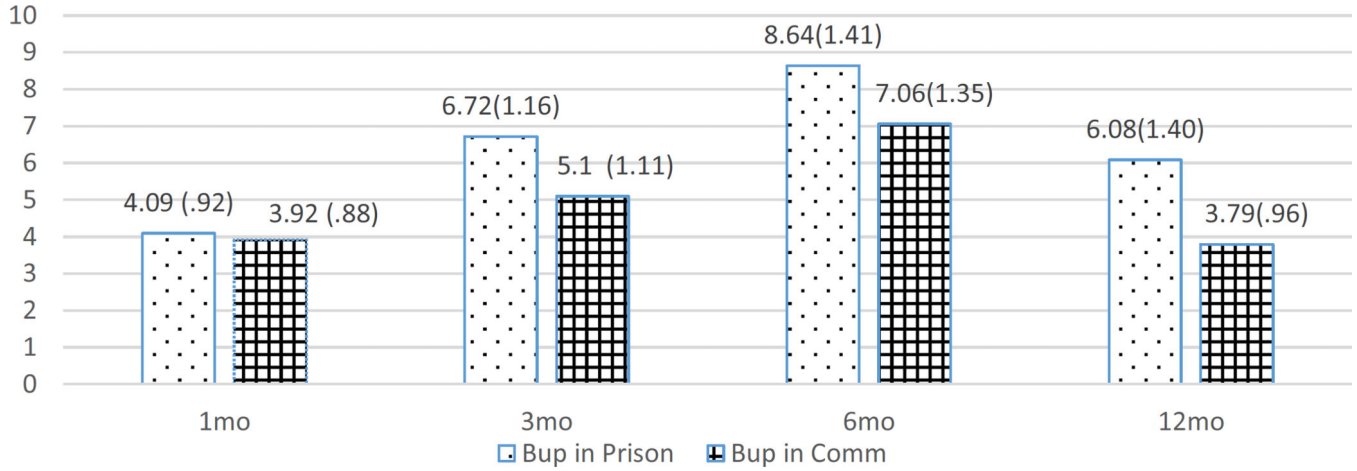

Figure 2. Self-reported heroin use in the past 30 days for Buprenorphine in Prison vs. Buprenorphine in the Community a,b,c

[a] Estimated Marginal Means (Standard Errors).

[b] past 30 days at 1,3,6,12-month post release. Adjusted for days at risk in the community.

[c] Self-reports

1-month: 204 participants were interviewed. 7 were not interviewed due to: received additional prison time (n=3), unable to locate (n=3), detainer in another state (n=1)

3-month: 204 participants were interviewed. 7 were not interviewed due to: received additional prison time (n=3), unable to locate (n=3), detainer in another state (n=1)

6-month: 176 participants were interviewed, 35 were not interviewed due to: received additional prison time (n=3), unable to locate (n=3), detainer in another state (n=1), Incarcerated/located at later follow-up (n=28)

12-month: 150 participants were interviewed. 61 individuals were not interviewed due to: received additional prison time (n=3), unable to locate (n=3), detainer in another state (n=1), incarcerated/located at later follow-up (n=54).

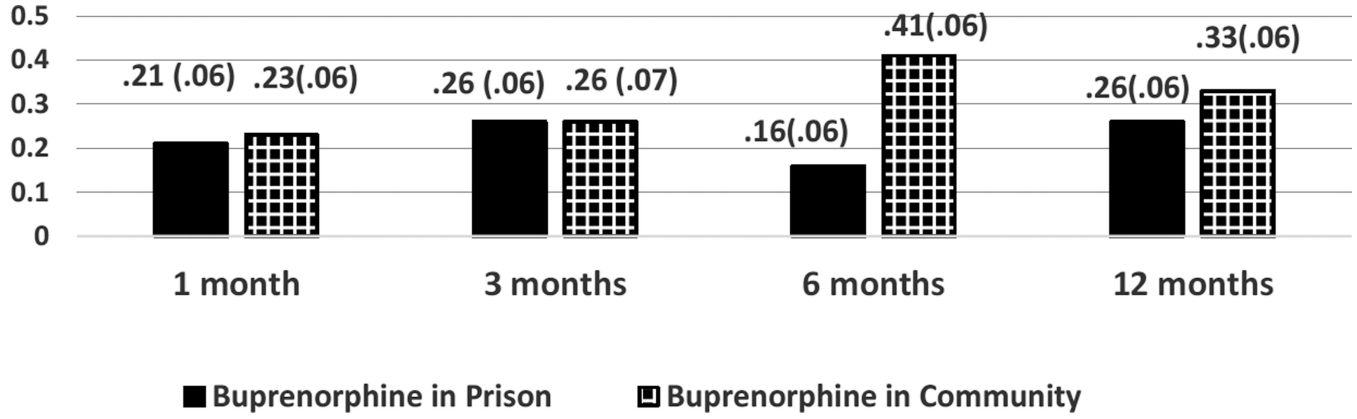

Figure 3. Estimated Marginal Means (Standard Errors) for opioid-positive urine screening test results by Buprenorphine in Prison vs. Buprenorphine in the Community

Urine testing proportion of positive and negative results for those tested at each follow-up time point:

1-month: Buprenorphine in prison (16/68, 23.5%) vs. Buprenorphine in the community (17/69, 24.6%); tested positive for other opioids only (n=5).

3-month: Buprenorphine in prison (21/73, 28.8%) vs. Buprenorphine in the community (25/74, 33.8%); tested positive for other opioids only (n=4).

6-month: Buprenorphine in prison (22/70, 31.4%) vs. Buprenorphine in the community (29/70, 41.4%); tested positive for other opioids only (n=5).

12-month: Buprenorphine in prison (18/61, 29.5%) vs. Buprenorphine in the community (21/63, 33.3%) tested positive for other opioids only (n=3).

Urine testing missing:

1-month: 137 samples analyzed, Results missing for 74 due to: missed interview window (n=55), incarcerated (n=10), unable to locate (n=3), refused (n=3), specimen leaked/lost (n=2), detainer in another state (n=1).

3-month 147 samples analyzed. Results missing for 64 due to: missed interview window (n=33), incarcerated (n=25), unable to locate (n=3), detainer in another state (n=1), phone interview (n=1), refused (n=1)

6-month: 140 samples analyzed. Results missing for 71 due to: incarcerated (n=42), missed interview window (n=17), phone interview (n=3), unable to locate (n=3), refused (n=2), no record (n=2), medical (n=1), detainer in another state (n=1)

12-month: 124 samples analyzed. Results missing for 87 due to: incarcerated (n=79), unable to locate (n=3), phone interview (n=2), medical (n=1), detainer in another state (n=1), no record (n=1).

Table 1

Selected background characteristics by In-Prison Treatment and Post-Release Service Setting Conditions

	Buprenorphine +OTP (*n*=52)	**Buprenorphine +CHC (*n*=52)**	**Counseling Only +OTP (*n*=54)**	**Counseling Only +CHC (*n*=53)**	**Total Sample (N=211)**
Categorical Variables, *n* (%)					
Gender					
Female	15 (28.9)	17 (32.7)	16 (29.6)	15 (28.3)	63 (29.9)
Male	37 (71.2)	35 (67.3)	38 (70.4)	38 (71.7)	148 (70.1)
Race					
African American	41 (78.9)	30 (57.7)	42 (77.8)	35 (66.0)	148 (70.1)
Caucasian	9 (17.3)	20 (38.5)	11 (20.4)	14 (26.4)	54 (25.6)
Other	2 (3.8)	2 (3.9)	1 (1.9)	4 (7.6)	9 (4.3)
Prior drug treatment	40 (76.9)	44 (84.6)	46 (85.2)	43 (81.1)	173 (81.9)
Prior buprenorphine treatment	7 (13.5)	7 (13.5)	6 (11.11)	12 (22.6)	32 (15.2)
Continuous Variables, *M (SD)*					
Age	39.15 (7.5)	39.18 (8.7)	39.55 (10.0)	38.42 (9.1)	39.08 (8.8)
Age first cocaine use	21.02 (7.4)	20.76 (7.6)	21.37 (5.0)	23.65 (13.2)	21.70 (8.8)
Age first heroin use	18.08 (5.9)	20.08 (6.1)	20.17 (6.2)	18.85 (5.4)	19.30 (5.9)
Age first crime	13.59 (6.4)	14.81 (8.5)	13.04 (4.7)	13.43 (4.4)	13.71 (6.2)
Number of prior incarcerations	8.06 (6.4)	8.86 (12.1)	6.24 (3.7)	6.34 (3.4)	7.35 (7.2)
Heroin use days[a]	24.13 (10.0)	24.21 (10.2)	23.83 (11.0)	25.60 (9.3)	24.45 (10.1)
Cocaine use days[a]	9.69 (12.8)	12.65 (12.9)	13.50 (13.5)	11.53 (13.2)	11.86 (13.1)
Crime days[a]	19.85 (12.9)	18.35 (12.8)	19.48 (12.9)	24.36 (15.3)	20.53 (13.6)

[a] past 30 days prior to index incarceration.