Drug and Alcohol Dependence 172 (2017) 34–42

Contents lists available at ScienceDirect

Drug and Alcohol Dependence

journal homepage: www.elsevier.com/locate/drugalcdep

Full length article

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

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ARTICLE INFO

Article history:
Received 12 July 2016
Received in revised form
22 November 2016
Accepted 26 November 2016
Available online 11 January 2017

Keywords:
Buprenorphine
Prisoners
Heroin addiction
Opioid substitution therapy

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) × 2 [Post-Release Service Setting Condition: Opioid Treatment: Program (OTP) vs. Community Health Center (CHC)] × 2 (Gender) factorial design. The trial was conducted between September 2008 and July 2012. Follow-up assessments were completed in 2014. Participants were recruited from two Baltimore pre-release 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 ($P = 0.005$). 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 $Ps > 0.14$) and no statistically significant hypothesized gender effects (all $Ps > 0.18$).
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.

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; Merrall 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

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http://dx.doi.org/10.1016/j.drugalcdep.2016.11.037
0376-8716/

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., 2015). 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, 2009, 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; Friedmann 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 pre-release 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, 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) × 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 3–9 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 kid-