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A randomized clinical trial of methadone maintenance for prisoners: Results at 1-month post-release☆

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Abstract

Background: Despite its effectiveness, methadone maintenance is rarely provided in American correctional facilities. This study is the first randomized clinical trial in the US to examine the effectiveness of methadone maintenance treatment provided to prisoners with pre-incarceration heroin addiction.

Methods: A three-group randomized controlled trial was conducted between September 2003 and June 2005. Two hundred eleven Baltimore pre-release inmates who were heroin dependent during the year prior to incarceration were enrolled in this study. Participants were randomly assigned to the following: counseling only: counseling in prison, with passive referral to treatment upon release ($n = 70$); counseling + transfer: counseling in prison with transfer to methadone maintenance treatment upon release ($n = 70$); and counseling + methadone: methadone maintenance and counseling in prison, continued in a community-based methadone maintenance program upon release ($n = 71$).

Results: Two hundred participants were located for follow-up interviews and included in the current analysis. The percentages of participants in each condition that entered community-based treatment were, respectively, counseling only 7.8%, counseling + transfer 50.0%, and counseling + methadone 68.6%, $p < .05$. All pairwise comparisons were statistically significant (all $ps < .05$). The percentage of participants in each condition that tested positive for opioids at 1-month post-release were, respectively, counseling only 62.9%, counseling + transfer 41.0%, and counseling + methadone 27.6%, $p < .05$, with the counseling only group significantly more likely to test positive than the counseling + methadone group.

Conclusions: Methadone maintenance initiated prior to or immediately after release from prison appears to have beneficial short-term impact on community treatment entry and heroin use. This intervention may be able to fill an urgent treatment need for prisoners with heroin addiction histories.

Keywords: Methadone maintenance; Drug abuse treatment; Prisoners; Heroin addiction

1. Introduction

Heroin dependence is a significant problem among individuals entering jails and prisons throughout the world. In the United States, approximately 12–15% of these individuals have histories of heroin addiction (Chaiken, 2000; Karberg and James, 2005); epidemiological studies of prisoners in England and Wales (Strang et al., 2006) and Italy (Rezza et al., 2005) report lifetime prevalence rates of 58% and 34%, respectively; and prisoners in the United States, Australia, and various European nations have higher rates of heroin use than the general population (McSweeney et al., 2002). Furthermore, re-addiction usually occurs within 1 month of release (Kinlock et al., 2002; Maddux and Desmond, 1981; Nurco et al., 1991). Although addiction is associated with a high risk of human immunodeficiency virus (HIV; Chitwood et al., 1998; Inciardi et al., 1998), hepatitis B and C infections

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(Edlin, 2002; Fuller et al., 1999; Hagan et al., 2002), overdose death (Mark et al., 2001; Weatherburn and Lind, 1999), criminal activity (Chaiken and Chaiken, 1990; Kinlock et al., 2003; Nurco, 1998), and re-incarceration (Substance Abuse and Mental Health Administration (SAMHSA), 2000), most re-entering prisoners do not receive substance abuse treatment while incarcerated or upon release (Inciardi et al., 1998; McSweeney et al., 2002; Smith-Rohrberg et al., 2004). Thus, there is an urgent need to evaluate promising treatments spanning incarceration and the community (Office of National Drug Control Policy (ONDCP), 2001a).

Despite extensive evidence of methadone treatment's effectiveness in community-based settings (Ball and Ross, 1991; Dole and Nyswander, 1965; Jaffe and Senay, 1971; Johnson et al., 2000; Joseph et al., 2000; Platt et al., 1998) and its widespread use in correctional facilities throughout the world (Jurgens, 2004; McSweeney et al., 2002), provided in 23 countries (European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), 2002), methadone treatment is rarely offered in U.S. correctional facilities. In the U.S., there are two types of correctional facilities—jails, typically administered by city or county governments, holding short-term inmates awaiting trials or serving shorter sentences and prisons, generally administered by state and federal governments and holding longer-term inmates serving sentences longer than 1 year. In 1968, Dole et al. (1969) conducted the first study of methadone treatment in an American correctional facility. In this study, 28 heroin-addicted pre-release New York City jail inmates were randomly assigned to methadone maintenance 10 days prior to release, with post-release assignment to continue treatment in the community or to an untreated control condition. Participants receiving methadone had lower re-addiction and re-incarceration rates at 7–10 months post-release than controls. Subsequently, New York City's jail began a methadone program in 1987. This program provides methadone treatment to newly-arrived jail inmates who are either addicted to heroin or who are receiving methadone maintenance treatment at the time of incarceration. This program has been effective in facilitating post-release treatment attendance and in reducing re-incarceration (Magura et al., 1993; Tomasino et al., 2001).

Baltimore's serious, persistent health and crime problems associated with heroin addiction (Fuller et al., 1999; Gray and Wish, 2001; Kinlock et al., 2002; Wish and Yacoubian, 2001) led to a small-scale study of prison-initiated opioid maintenance treatment with Levo-alpha-acetylmethadol (LAAM) for male inmates with pre-incarceration heroin dependence (Kinlock et al., 2002). Results indicated that it was feasible to enroll such inmates in maintenance treatment, and that this approach facilitated treatment entry upon release to the community (Kinlock et al., 2002, 2005a,b).

The present study is, to our knowledge, the first randomized clinical trial in the United States to examine the effectiveness of prison (as opposed to jail)-initiated methadone (Kinlock et al., 2005b). It was conducted to assess the extent to which initiating methadone in prison prior to release with continued treatment in the community would be more efficacious than initiating methadone treatment in the community or simply providing counseling in prison with a passive referral to treatment upon release. Determining the differences in efficacy among these conditions would provide important data to clinicians, policy makers, and correctional officials. The present report focuses on outcomes at 1-month post-release—the time point by which an estimated 66–78% of untreated prisoners with heroin addiction histories typically relapse (Maddux and Desmond, 1981; Nurco et al., 1991).

2. Method

2.1. Participants

Participants were recruited between September 2003 and June 2005 from male prisoners in a Baltimore pre-release facility who had been incarcerated at least 1 year and would have met criteria for methadone maintenance treatment at the time of their incarceration. Eligibility criteria were: (1) 3–6 months before anticipated release from prison; (2) meeting diagnostic and statistical manual of mental disorders (DSM-IV; American Psychiatric Association, 1994) criteria of heroin dependence at time of incarceration and being physiologically dependent during the year prior to incarceration; (3) suitability for methadone maintenance as determined by medical evaluation; (4) willingness to enroll in a prison-based methadone maintenance treatment program; and (5) residing in Baltimore following release. Individuals who did not meet the heroin dependence criterion were eligible if they were enrolled in an opioid treatment program in the year before incarceration. Individuals were excluded from participation if they had one or more of the following conditions: (1) renal failure; (2) liver failure; (3) pending/unadjudicated charges, which could have resulted in transfer to another correctional facility and/or additional prison time; and (4) a pending parole hearing.

Participants were recruited by group orientation sessions (in which research staff informed potential participants about the nature of the study and requirements for participation) and word-of-mouth. Inmates willing to enroll were individually screened for participation by study personnel. Inmates still eligible at this point then met with research staff for informed consent and completed baseline assessments (see Section 2.4). Final consent and determination for study enrollment was made by the methadone program's medical director following a physical examination (see consort diagram, Fig. 1).

Of the 253 individuals who were consented and completed a baseline assessment, the 211 who were randomized were compared on the baseline variables presented in Table 1 with the 42 who became ineligible for study participation. There was only one statistically significant difference between the two groups. Individuals who were randomized reported committing crime on more days in the last 30 days in the community before the current incarceration than did those not randomized ($p = .006$).

2.2. Study design

The study was a three-group randomized controlled trial. Participants were assigned (see Fig. 1) to one of three treatment conditions based on a block randomization procedure, such that in a block of nine participants, three participants were assigned at random to each of the three treatment conditions. Assessments were conducted at baseline and at 1 month following release from prison. The study protocol was approved by Friends Research Institute's institutional review board (IRB) and the trial was monitored by an external data and safety monitoring board (DSMB).

2.3. Interventions

Following initial screening, informed consent, and physical examination, consenting participants were randomly assigned to one of three conditions: counseling only—counseling in prison, with passive referral to treatment upon release; counseling + transfer—counseling in prison, with immediate access to methadone maintenance treatment upon release from prison, but no maintenance treatment in prison; or, counseling + methadone—initiation of