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Treatment initiation strategies for syringe exchange referrals to methadone maintenance: A randomized clinical trial

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ABSTRACT

This randomized clinical trial evaluated the efficacy of three treatment initiation strategies for improving retention to methadone maintenance for opioid-dependent individuals referred from a syringe exchange program (SEP). New admissions (n = 212) were randomly assigned to one of three 3-month initiation strategies: 1) Low Threshold (LTI), 2) Voucher Reinforcement (VRI), or 3) Standard Care (SCI). LTI was modeled on interim methadone maintenance to transition SEP admissions to the structure of medication-assisted treatment while maximizing exposure to methadone pharmacotherapy. VRI used monetary incentives to reinforce adherence to pharmacotherapy and adaptive counseling. SCI participants received standard methadone dosing and adaptive counseling. All participants were stabilized on methadone pharmacotherapy with a target dose of 80 mg. Following the initiation phase, participants in each condition received standard adaptive counseling from months 4–6. Results showed that most participants failed to achieve the target methadone dose. While no condition differences were observed in retention rates over the 3-month and 6-month observation periods, participants across conditions exhibited reductions in objective and self-report measures of drug use. Results support the benefits of referring syringe exchangers to methadone maintenance, and demonstrate the challenge of retaining these individuals in treatment.

1. Introduction

Over 200 syringe exchange programs (SEPs) operate in the United States (Bramson et al., 2015). SEPs are associated with reduced rates of HIV transmission and risk behaviors among people who inject opioids (Aspinall et al., 2014; Palmateer et al., 2010). Despite these important reductions, sustained opioid use in this population can lead to unsafe injection behaviors and drug overdose (Des Jarlais et al., 2007; Fisher et al., 2003; Hser et al., 2001). The referral and admission of SEP participants to opioid-agonist treatment programs creates an opportunity to further reduce risk behavior and mortality through greater reduction of drug use and improved psychological and social functioning (Gowing et al., 2011; Kidorf et al., 2011b; McLellan et al., 2000). Most SEPs offer referrals to substance use disorder treatment (Bramson et al., 2015; Des Jarlais et al., 2009), and the SEP setting provides an opportunity to deliver interventions that enhance rates of treatment enrollment (e.g., Kidorf et al., 2009).

While SEP participants appear to attain a number of measurable benefits from substance use disorder treatment, including significant reductions in drug use and improved psychosocial functioning (Brooner et al., 1998; Kidorf et al., 2009, 2012), they unfortunately drop out of treatment more quickly than non-SEP referrals (Kidorf et al., 2011a; Neufeld et al., 2008). This might be partially accounted for by the fact that SEP participants enter treatment with higher rates of drug use and associated risk behaviors than other treatment-seeking opioid users (Grau et al., 2005; Wood et al., 2007). Greater drug use severity on admission and over the course of treatment is commonly associated with lower rates of retention in SEP participants and other substance users (Neufeld et al., 2008; Proctor et al., 2015).

Among the benefits of remaining in treatment longer are sustained exposure to opioid agonist medications and professional treatment providers. Patients retained in treatment have more opportunity to address concerns that frequently correlate with chronic drug use, including medical, psychiatric, housing, legal and employment problems (McLellan et al., 2000). They are also protected from the adverse impact of treatment drop-out that is frequently associated with increased drug use, mortality, and risks of transmitting HIV-infection and other blood-borne pathogens to self or others (Gibson et al., 2008; Sordo et al., 2017; Zaric et al., 2000). Only the combination of SEP participation with uninterrupted methadone treatment reduced incidence of

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HIV-infection of injection drug users in Amsterdam (Van Den Berg et al., 2007).

A potentially beneficial strategy to enhance treatment retention in this population is to use treatment initiation interventions to transition opioid users from syringe exchange participation to the more demanding intervention of methadone maintenance. The use of role induction interventions to improve early response to treatment has its roots in the general psychiatric literature (e.g., Hoehn-Saric et al., 1964). As applied to substance use disorder treatment, role induction interventions clarify and simplify the demands and process of treatment, and address common misperceptions and potential obstacles to seeking help (Katz et al., 2004; McCarty et al., 2007; Walitzer et al., 1999).

The present study evaluates two treatment initiation strategies designed specifically for SEP participants entering methadone maintenance. The first is low threshold treatment initiation. This treatment initiation strategy is based on low threshold methadone treatment approaches that reduce programmatic requirements that many patients find undesirable (e.g., weekly rates of scheduled counseling) in an effort to enhance exposure to the positive reinforcing and therapeutic effects of methadone (Kourounis et al., 2016; Strike et al., 2013). Low threshold methadone treatment has been associated with good retention, and reductions in HIV-risk behaviors and opioid use (Deck and Carlson, 2005; Gruber et al., 2008; Millson et al., 2007). Additional support for low threshold interventions comes from studies showing that agonist medications and minimal schedules of counseling can be administered safely to opioid users waiting to begin routine agonist-based treatment (e.g., Schwartz et al., 2006, 2011; Sigmon et al., 2016).

The second treatment initiation strategy evaluated in this study is voucher-based reinforcement contingent on treatment engagement. There is a substantial literature on the benefits of using voucher reinforcement to motivate behavior change in opioid-dependent and other populations of substance users (Davis et al., 2016). While most of these studies have used behavioral reinforcement strategies to specifically reduce rates of drug use, a secondary outcome is improved treatment retention (Lussier et al., 2006). In addition, a growing number of voucher reinforcement studies have targeted other important therapeutic outcome and process measures, including attendance to counseling and utilization of other treatment resources (e.g., Kidorf et al., 2013; Petry et al., 2006). This type of behavioral strategy appears well suited to SEP participants who may be more responsive to incentives placed on attendance and retention versus drug use (Kidorf et al., 2009). The emphasis on improving treatment engagement is also supported by findings from studies showing that engagement early in treatment is associated with improved longer-term outcomes (Gossop et al., 2003; Joe et al., 1999; McCarty et al., 2007).

In the present randomized clinical trial, 212 people with opioid dependence referred by the Baltimore Needle Exchange Program (BNEP) to methadone maintenance were randomly assigned to one of three treatment initiation strategies for 3-months: 1) Low Threshold Intervention (LTI), 2) Voucher Reinforcement Intervention (VRI), and 3) Standard Care Intervention (SCI). Following the 3-month initiation phase, all participants were referred to routine adaptive care counseling schedules for an additional 3-months. We hypothesized that LTI and VRI participants would achieve higher rates of 3-month and 6-month treatment retention than SCI participants, while VRI participants would have lower rates of substance use than LTI participants.

2. Method

2.1. Participants

All participants (n = 212) were registered at the BNEP, which is operated by the Baltimore City Health Department. The BNEP uses a mobile van to provide a safe setting for injection drug users to exchange used syringes for sterile syringes, to receive safe injection kits, and to receive free HIV and HCV testing. BNEP staff referred registrants who injected heroin and expressed interest in treatment to the study research van (parked adjacent to the BNEP mobile van), where they were informed of the opportunity to enroll in opioid agonist treatment at Addiction Treatment Services (ATS). BNEP registrants were recruited from August 2010 to April 2015. Research staff scheduled an intake date (usually within one week), and informed BNEP registrants that following admission to the treatment program they would be asked to participate in a study that evaluated different strategies for starting methadone maintenance, though they would be under no obligation to join the study.

On the day of admission to ATS, these patients met with research staff to review the requirements, benefits, and risks of study participation. The inclusion criteria was referral from the Baltimore Needle Exchange Program. Exclusion criteria included the presence of a major mental illness or severe cognitive impairment that interfered with understanding and completing study procedures. The Johns Hopkins University School of Medicine Institutional Review Board and the Baltimore City Health Department approved the study. The clinicaltrial.gov identifier is NCT01142986.

Fig. 1 presents a consort flow-chart for study enrollment. Of the 223 participants that signed informed consent, 11 were ultimately withdrawn from the study prior to randomization and excluded from final analyses. Six participants left treatment against medical advice, three participants were removed due to acute psychiatric symptoms, one participant had transferred from another treatment facility, and one participant was transferred to another program due to health insurance coverage requirements, leaving 212 participants randomized to study conditions and included in data analyses. Participants completed about two-thirds of all follow-up assessments; missing data was evenly distributed across conditions $F(2, 211) = 0.38$, $p = 0.69$.

2.2. Assessments

Participants completed baseline assessments during the first week of study participation. The Structured Clinical Interview for the DSM-IV-R (SCID-I and SCID-II; First et al., 1995) was administered to assess the presence of a current DSM-IV Axis I psychiatric disorder; the SCID-II was used only for evaluating the diagnosis of Antisocial Personality Disorder. The Addiction Severity Index (ASI; McLellan et al., 2006) was administered at baseline and monthly thereafter to assess problem severity in seven areas commonly affected by substance use. The present study employed alcohol use and drug use ASI composite scores. Those leaving treatment early had the opportunity to return to the program to complete the ASI at the scheduled time. Participants were compensated $15.00 per hour for completing assessments. Finally, participants submitted urine samples for testing once per week using a modified random schedule (randomly testing on Mondays, Wednesdays, or Fridays). Urine samples were obtained under direct observation (through a one-way mirror) and tested at a certified laboratory that employed TLC and EMIT testing for the presence of opioids, cocaine, benzodiazepines, and cannabis. Participants leaving treatment against medical advice were not asked to submit additional urine samples.

2.3. Routine clinical procedures

2.3.1. ATS

ATS is a publicly-supported substance abuse treatment program in Southeast Baltimore. It provides medication-assisted treatment for about 350 patients. Most patients have health insurance that reimburse for substance use disorder treatment. Patients without health insurance, and those with insurance that did not cover program charges, were covered via our grant-supported treatment slots that include a state supported sliding fee schedule. This schedule uses differing intersections of annual income and number of dependents in determining the adjusted charge. The low end of the sliding schedule at the time of this