Published in final edited form as:
Subst Abus. 2012 ; 33(1): 48–59. doi:10.1080/08897077.2011.609438.

A Multi-Site Pilot Study of Extended-Release Injectable Naltrexone Treatment for Previously Opioid-Dependent Parolees and Probationers

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Abstract

A feasibility study was conducted to pilot test the ability of five sites to recruit, treat, and retain opioid-dependent offenders in a trial of extended-release injectable naltrexone (XR-NTX). The participants, 61 previously opioid-dependent individuals under legal supervision in the community, received up to six monthly injections of Depotrex® brand naltrexone and completed a six-month follow-up interview. Six-month outcomes showed that those who completed treatment had significantly fewer opioid-positive urines and were less likely to have been incarcerated than those who had not completed treatment. The findings indicate that XR-NTX holds promise as a feasible, effective treatment option for opioid-dependent offenders.

Keywords

Extended-release Naltrexone; Depotrex®; Offenders; Opioid Dependence; Addiction Pharmacotherapy; Heroin

INTRODUCTION

Opioid dependence is a chronic relapsing disease often associated with an increased frequency of criminal behavior resulting in severe legal consequences, including incarceration. Cyclic patterns of relapse, criminal behavior, and re-incarceration are common.(1–3) In addition to legal problems, the opioid-dependent individual suffers many

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adverse health and social consequences of addiction, including HIV and hepatitis C infection, as well as unemployment and family problems.(2)

Despite the well-established link between opioid addiction and crime, relatively few addiction pharmacotherapy studies have been conducted within the criminal justice setting, particularly in the United States.(3) Concerns stemming from prior past abuses of prisoners, including failure to obtain informed consent, sensitivity, and ethical concerns, have constrained medication research with this vulnerable population.

Treatments such as methadone(4,5) and buprenorphine(6) are efficacious for opioid dependence in terms of maintaining patients in treatment and reducing heroin use and criminal activity, primarily in the community and, more recently, in criminal justice settings.(3,7–9) However, these opioid receptor agonist medications have limitations. For example, there is evidence that some patients continue to use illicit drugs (mainly cocaine) while receiving these treatments.(2,10–12) In addition, patients cite barriers to methadone maintenance treatment (MMT) such as the daily dosing regimens that often hamper employment efforts,(13) the fear of prolonged withdrawal if they are detoxified from the medication,(14) especially in jail, and negative attitudes and myths surrounding methadone treatment.(15) Moreover, since these agonist treatments produce opioid effects similar to heroin and can be abused and diverted, they have not been universally accepted by the criminal justice system.(16–19)

Maintenance therapy with naltrexone, an opioid receptor antagonist medication, is an underutilized alternative for opioid-dependent persons. Unlike methadone or buprenorphine, naltrexone blocks the intoxicating and reinforcing effects of opioids and has virtually no psychotropic or euphoric effects. Naltrexone does not induce physical dependence, and there is therefore no withdrawal when it is stopped. However, many who provide treatment to offenders are not aware of the medication or may erroneously believe it to be similar to the agonist treatments.

Our work with naltrexone has involved both the oral and the extended-release formulations that include Vivitrol® and Depotrex®. The frequent dosing required for oral naltrexone (daily or multiple times per week) results in lack of patient adherence to the medication. Technology has been developed that enables naltrexone to be prepared in an extended-release injectable formulation (XR-NTX). This extended-release formulation removes barriers to medication compliance since it can provide effective blood levels for 30 days or more following a single injection. Vivitrol® which is manufactured by Alkermes is administered as an intramuscular injection, whereas Depotrex® which was manufactured by Biotek is administered as a subcutaneous injection. Only Vivitrol® is currently available in the United States and Europe and has recently received FDA approval for opioid addiction. The safety of XR-NTX has been demonstrated in alcoholic patients indicating that it is well tolerated(20) with no evidence of hepatotoxicity.(21,22)

Our prior work with oral naltrexone in the United States Federal Probation Offices demonstrated that 34 probationers who received oral naltrexone significantly reduced their use of opiates over the course of six months of treatment compared to 17 probationers who did not receive oral naltrexone (8% versus 30%)(23) Of those receiving oral naltrexone, 26% had their probation revoked compared to 56% of the control group.

Based upon the promising findings from these pilot results, a larger study was conducted comparing the outcomes of 111 subjects who were randomized to six months of either 300 mg per week of oral naltrexone (150 mg twice a week) plus psychosocial treatment as usual (n=56) or standard psychosocial treatment as usual (TAU) without naltrexone (n=55). Whereas the study conducted by the Federal Probation Offices included only federal

probationers, the more recent study(24) involved participants from city and federal programs. The results of this larger, more mixed group failed to show a significant advantage for the patients randomized to oral naltrexone in terms of retention, crime, and urine tests negative for opiates.(24) While naltrexone subjects retained in treatment used less opiates than the TAU subjects who were also retained in treatment, both groups experienced substantial dropout, an outcome that made it difficult to separate group differences from the selective effects of drop out. The major difference in the two studies was that supervision was more closely monitored in the federal probation system than in the more diverse setting of city and federal programs. Based on the findings from the second study, we believe that the success of oral naltrexone would require much more supervision than is typically provided by the criminal justice system. It is anticipated that XR-NTX could be substantially more effective than oral naltrexone despite variation in levels of supervision. Its long duration of action has the potential to improve retention and reduce the likelihood of relapse.

Extended-release naltrexone was tested in a collaborative study between Columbia University and the University of Pennsylvania(25) with 60 heroin-dependent non-offenders who were treated for two months. The study used Depotrex®, the Biotek version of extended-release naltrexone, and demonstrated that, over the two-month treatment period, injectable long-acting naltrexone was well tolerated and produced a significant dose-related increase in treatment retention compared to placebo.

More recently, preliminary findings from a double-blind, randomized multi-site trial of 250 opioid-dependent patients in Russia found that patients treated with Vivitrol® brand XR-NTX had significantly fewer opioid positive urines, better treatment retention, and reduced cravings for opioids compared to patients who received a placebo.(26)

Since opioid-addicted individuals under criminal justice supervision are considered a vulnerable population there has been limited research, making it important to study medication treatments in this group. It is also important to understand the generalizability of the treatment across a range of real world treatment settings. Therefore, in order to obtain a sufficient generalizable sample, a multi-site feasibility study was conducted to assess our ability to recruit, treat, and retain opioid-dependent offenders in this pilot study of Depotrex® brand XR-NTX. The five sites included: 1) University of Pennsylvania, (Penn; coordinating site), 2) New York University/Bellevue (NYU), 3) Rhode Island Hospital, 4) Columbia University, and 5) Friends Research Institute in Baltimore. The primary study outcomes were retention in the six month treatment program, opioid use, and incarcerations. It was anticipated that participants who received all six monthly injections of XR-NTX would have fewer opioid positive urines and experience less recidivism that those who did not complete the treatment protocol.

METHODS

Subjects

The participants in this study were 61 previously or recently opioid-dependent individuals who were under legal supervision in the community. By legal supervision we mean that participants could be on probation or parole or involved in diversion programs such as a drug court as well as other disposition programs that offer alternatives to incarceration or early parole. All subjects were volunteers who consented to participate in a clinical trial of extended-release naltrexone. Special efforts were made to assure offenders that participation in the research study was voluntary, and they were instructed that participation in the research was an additional service they could receive. All potential subjects were informed that choosing to participate or not participate in the trial would have no effect on their probation or parole status and they could stop participation in the study at any time without

affecting their treatment or criminal justice status. Individuals not participating in the study were referred to other types of treatment in the community.

Individuals were eligible for participation if they: 1) signed an informed consent form; 2) were between the ages of 18 and 55; 3) had a diagnosis of opioid dependence according to DSM-IV criteria; 4) were in good general health as determined by complete physical examination and laboratory tests; 5) had been under legal supervision in the community for a period of at least six months; and 6) had a negative result for urinary opioids and self-reported being at least 3 days opioid-free.

Individuals with the following characteristics were excluded from study participation: 1) current severe alcohol dependence that required medical supervision for alcohol withdrawal; 2) current psychosis, dementia, mental retardation, or history of schizophrenia; 3) significant clinical abnormalities in hematology, chemistry, or urinalysis; 4) significant clinical cardiovascular, neurological, hepatic, renal, pulmonary, metabolic, endocrine, or gastrointestinal disorders; 5) current diagnosis of chronic pain disorder; 6) female subjects who were pregnant or lactating, or women of childbearing potential who were not using birth control; and 7) subjects who had taken an opioid antagonist within the prior 6 months.

Participant Recruitment and Screening

A total of 35 subjects were recruited from the Penn site, eight from NYU, seven from Rhode Island, seven from Columbia, and four from Baltimore.

University of Pennsylvania—Study participants were recruited from various sources, including community-based drug treatment programs (n=12), inpatient programs and detoxification units (n=7), the federal probation and parole office (n=5), and Philadelphia County probation or parole officers (n=3). One individual was recruited from an alternative disposition program that offered early parole if participants agreed to attend a mandated substance abuse treatment program, and another was recruited from an intermediate punishment program (IPP) that provided offenders the option of attending mandated treatment in lieu of incarceration. An additional six participants were self-referrals from newspaper advertisements (n=3) or word-of-mouth referrals from other participants (n=3).

At the Penn site, a total of 336 potential subjects were screened, 89 consented, and 35 were enrolled and injected. Twenty of the consented candidates did not complete screening because they dropped out during the baseline evaluation. Other individuals were unable to provide an opioid-free urine (n=8); decided they were no longer interested in receiving the medication (n=7); or were excluded due to legal (e.g., none or not enough probation/parole; n=6), psychiatric (n=6), or medical reasons (n=3). Additional candidates were not enrolled for various other reasons (n=4).

New York University—Potential subjects were recruited through local institutional and citywide outreach efforts, including flyers, letters to treatment programs, in-person ‘detailing’ of program staff, and by encouraging word-of-mouth referrals by active patients. Recruitment was most successful in two locations: the hospital emergency detoxification unit (2 of 8 patients), and an area treatment program catering to a parole population and offering comprehensive outpatient psychosocial treatment, vocational training, and supportive housing (6 of 8 patients). A total of 37 potential candidates were screened, ten consented, and eight were enrolled. One of the consented candidates failed screening due to lack of opioid dependence and the other had an insufficient amount of time left under community supervision.

Rhode Island Hospital—Advertisements were placed in local rehabilitation and detoxification facilities in the Greater Providence area. The majority of participants enrolled were recruited from word-of-mouth as news of a new treatment option spread through the opiate dependent community. A total of 34 individuals were screened, 11 consented, and seven enrolled. Among the four candidates who failed screening, two did not return to complete the baseline evaluations and two were excluded for medical reasons.

Columbia University—All of the participants who were screened at the Columbia site were referred by local community treatment programs. A total of 13 were screened, 10 consented, and seven were enrolled. Among the three who failed screening, one had to be excluded for medical reasons, one declined participation after consent, and a third did not return after consent.

Friends Research Institute—In Baltimore, three out of the four enrolled subjects were recruited from newspaper advertisements, and one participant was recruited from a residential treatment program. A total of 48 candidates were screened, 12 consented, and four were enrolled. Five of the eight consented candidates who did not enroll failed screening due to not showing up for appointments after the initial consent. Two individuals did not receive the medication because of medical issues, and one person died in a fire before the first injection.

Human Subjects Approvals

The project was approved by the Institutional Review Boards at each of the participating sites as well as the City of Philadelphia. The research was also approved by an administrative board consisting of the Chief Federal District Court Judge in Philadelphia and by a research review committee of one of the inpatient hospital programs at Penn.

Participant enrollment

Interested candidates were given a complete description of the study by research staff. Individuals who agreed to participate in the study signed an informed consent document at the point of entry into the trial. Next, potential participants were scheduled to undergo a two to three day screening process to determine eligibility for the study. Physical exams and laboratory tests were assessed to ensure that each potential subject was in good general health and had normal hepatic function. The Mini-International Neuropsychiatric Interview (MINI)(27) for the DSM-IV was administered to ensure that each potential subject had a history of opioid dependence and to rule out any severe psychiatric disorders.

During the screening process, potential participants also completed a series of baseline research assessments. These assessments included the Addiction Severity Index-Lite (ASI-Lite),(28,29) Risk Assessment Battery (RAB),(30) and Timeline Followback (TLFB)(31) In order to begin treatment, potential participants had to self-report that they had not used opioids for at least three days and had to provide a negative urine result for opioids immediately prior to receiving their first injection.

Finally, prior to receiving their first injection, potential subjects who provided an opioid-free urine received a challenge test consisting of 0.8 mg of naloxone administered intravenously or intramuscularly followed by a 20-mininute observation period during which the individual was evaluated for signs and symptoms of opioid withdrawal. Individuals who failed the naloxone challenge test were re-evaluated to determine if they required additional days of abstinence prior to re-challenge or were referred to a substance abuse detoxification program. Individuals who successfully passed the naloxone challenge test were enrolled in the study and started immediately on XR-NTX.

After their initial injection, subjects were scheduled for research visits twice each week in which they provided a urine drug screen and were asked about any adverse events during the past week. Participants were also scheduled for a six-month follow-up evaluation where they were re-administered the ASI-Lite, RAB and TLFB and provided a urine drug screen. All participants were compensated for completing research assessments and for travel expenses at each evaluation time point. Data from all sites were entered through a secure web-based data entry system located at Penn.

Extended-release Naltrexone Treatment

The XR-NTX used in this trial was Depotrex®, manufactured by Biotek, Inc. (Woburn, MA), and was approved by the FDA for use in clinical trials under IND #38,275. All doses of XR-NTX were 228 mg and were administered by a project physician or by the study nurse practitioner during scheduled research visits. The initial dose of XR-NTX was administered by subcutaneous injection into the gluteal (buttock) muscle. Subsequent injections of naltrexone occurred approximately 30 days apart for months two through six. Alternate gluteal muscles were used for each month's injection. At the beginning of the sixth month, subjects were given their last dose (#6) of XR-NTX. At the six-month follow-up subjects received a physical examination and repeated baseline laboratory tests. (N.B.: The NYU site administered a total of three injections during a three-month treatment period and completed a six-month follow-up).

Data Analysis

Outcome data will be presented for all five sites and then again separately for the Penn site. Participants who completed all XR-NTX injections were compared to those who did not receive all injections. Therefore, Penn, Rhode Island, Columbia and Baltimore completers were defined as those who received all six injections. For NYU, completers were defined as those who received all three injections. Comparisons between the completer and non-completer groups used chi-square tests to assess the significance of the binary outcomes of opioid use (positive/negative), any incarceration in the six-month treatment period (yes/no), and employment at six months (working/not working).

RESULTS

Sample Characteristics

The majority of participants were male (92%), about one-half (51%) were Caucasian, 28% were African-American, and 20% were Hispanic (Table 1). The participants reported an average age of 37.5 years and 11.2 years of education. At study entry, one-third (33%) of the subjects were working and 15% were married.

On average, participants reported using heroin regularly for 12 years and other opiates for six years. They reported using cocaine for about seven years and alcohol for nearly 12 years. Overall, participants received an average of 6.9 prior drug treatments. About one-third of the respondents reported IV drug use (34%), 15% shared needles, and nearly one-half (47%) reported that they did not use condoms on a consistent basis in the six months prior to the baseline interview.

The majority of prior criminal charges were for drug offenses (72%). Sixty-percent of participants reported parole/probation violations, 42% had a burglary offense, 42% were charged with assault, 38% reported shoplifting/vandalism, and 33% were charged with robbery. The subjects reported an average of 13.1 prior charges and were incarcerated for an average of 42 months.

Participants from all sites were compared on the variables presented in Table 1 (i.e., demographics, drug history, HIV risk and criminal history). Overall, the characteristics of the five sites were similar, but there were a few exceptions. For example, there were proportionally more Hispanics enrolled at the Columbia site (χ^2=33.9, df=12, p=.001) compared to the other sites. Participants at the Penn site had a slightly higher average education level than subjects at the Columbia site (F=4.2, df=59, p=.005), and NYU's participants reported a greater length of prior incarcerations (nearly seven years) compared to Penn and Baltimore. (F=5.4, df=59, p=.001).

Treatment Completion

As shown in Table 2, the percentage of participants who completed all six XR-NTX injections (across the four sites that provided up to six injections) was 40% (21/53). The average number of injections that subjects received was four. A total of 46% (16/35) of participants at the Penn site received all six XR-NTX injections. For subjects at the Penn site, the average number of injections received was four with nearly 60% of the participants receiving at least four injections. At the Baltimore site, two out of the four participants (50%) received all six injections, followed by Columbia (2/7; 29%) and Rhode Island (1/7; 14%). As mentioned previously, the NYU protocol consisted of a total of three injections, and all but one of the eight subjects receive all three injections (7/8; 88%). A total of eight participants (four at Penn, three in Rhode Island, and one at NYU) were incarcerated and were unable to complete their injections.

Six-Month Follow-up

All Sites—The overall six-month follow-up rate across all five sites was 66% (40/61) (Table 3). Nearly all the treatment completers (27/28; 96%) completed the six-month follow-up compared to 39% (13/33) of non-completers. This difference was statistically significant (χ^2=21.8, df=1, $p < .0001$). A total of 25 out of the 35 respondents (71%) completed a six-month follow-up evaluation at the Penn site. At NYU, a total of 7 out of 8 subjects (88%) completed a six-month follow-up evaluation. In Baltimore three out of four (75%) completed, at Columbia four out of seven (57%), and in Rhode Island one out of seven (14%) completed the follow-up. At the Rhode Island site, incarceration data were available for an additional three respondents.

Penn—All of the treatment completers (16/16) completed the six-month follow-up evaluation compared to just under one-half of the non-completers (9/19; 47%) (Table 3). This difference was statistically significant (χ^2=11.8, df=1, p =.001).

Opioid Use at Six-Month Follow-up

All Sites—Urine drug screen data were available for 35 out of the 40 subjects who completed a six-month follow-up. Urine data were not available for five subjects who completed the six-month follow-up because these individuals had become incarcerated. Overall, 14% of subjects provided an opioid-positive urine at follow-up (Table 3). Only one completer (4%) had an opioid-positive urine at six-months compared to 44% of the non-completers (χ^2 =9.0, df=1, p=.003).

Penn—Nine percent of subjects were positive for opioids. None of the treatment completers (0/16) had a positive urine for opioids at six months compared to 33% (2/6) of the non-completers (χ^2=5.9, df=1, p=.015).

Incarcerations During Six-Month Treatment Phase

All Sites—We were able to obtain incarceration data through criminal records for an additional five subjects who were not followed-up at six months. Therefore, we knew the incarceration status of 45 respondents (74%) across all five sites. Overall, 29% of the subjects were incarcerated at some point during the six-month treatment phase (Table 3). Significantly more non-completers (50%) were incarcerated during the six months of treatment compared to completers (15%) (χ^2 =6.5, df=1, p=.011).

Penn—Six subjects (6/26, 23%) were incarcerated at any point during the six-month active treatment phase. Of these six incarcerations, two subjects were incarcerated for a new charge, whereas four subjects were charged for a crime they committed prior to study enrollment. Only one treatment completer (1/16, 6%) was incarcerated during the six-month treatment phase compared to five out of 10 (50%) non-completers (χ^2=6.6, df=1, p=.010). The one treatment completer who was incarcerated was charged for a crime committed prior to study enrollment.

Employment at Six-month Follow-up

All Sites—One-half (50%) of subjects were employed at the six-month follow-up across all five sites (Table 3). While there were more completers who were working (56%) compared to non-completers (39%), this difference was not statistically significant (χ^2=1.0, df=1, p=.311).

Penn—Sixty percent of participants were employed at the end of treatment. Completers (75%) were significantly more likely to be employed compared to non-completers (33%) (χ^2=4.2, df=1, p=.041).

Adverse Events

There were two serious adverse events directly related to the medication. One participant was hospitalized for opioid withdrawal in response to the first dose of naltrexone. A second participant was hospitalized for an overdose of quetiapine taken in response to insomnia after the first dose of naltrexone. Another individual was hospitalized for suicidal ideations as a result of losing a family member. While we did not believe this was drug-related, as a precaution the person was subsequently taken off the medication. A total of four other patients required hospitalization while on XR-NTX for events that were unrelated to the medication (e.g., asthma attack) and three participants were hospitalized for similar unrelated events while not currently on study medication. Other adverse events included injection site events (itching, lump, or soreness) which were reported by 14 participants. Also, insomnia, headache, and nausea were reported, and possibly related, but there was no placebo group. Moreover, these complaints are common in opioid-dependent patients in the absence of any medication and in placebo-treated groups.

DISCUSSION

The feasibility of the study was clearly demonstrated. All sites were able to screen, recruit and treat eligible candidates, and there were only two serious medication-related adverse events.

Opioid-dependent individuals on probation or parole are a particularly difficult group to treat and generally have lower treatment completion rates than other drug-dependent offenders.(32) While methadone and buprenorphine treatments have proven efficacy, they are not desired by many opioid-dependent individuals.(33) Furthermore, in the United States, many jail and prison officials, including medical providers(17,34) and many

probation and parole officers(9,35) are not willing to refer probationers and parolees for agonist-based treatments. The clinical usefulness of oral naltrexone has been challenged due to poor adherence(36,37) and lack of acceptance, especially within the criminal justice setting.[19]

Although we cannot make a direct comparison between the prior Coviello et al.(24) randomized trial of oral naltrexone and the current pilot study of XR-NTX, it is important to note that treatment retention was better with the extended-release formulation. In the Coviello et al.(24) study, drop out was high with most participants dropping out within the first few weeks. In contrast, in the present XR-NTX study, nearly 60% of the participants at the Penn site were retained at least four months and 64% were retained at least three months across all five sites. The good overall retention rate with XR-NTX may have led to reductions in both relapse and re-incarceration among treatment completers.

In regard to relapse and re-incarceration, none of the Penn participants who received all six XR-NTX injections had a positive drug screen for opiates compared to 33% of those who did not receive the six-month treatment protocol. Moreover, the incarceration rate for those who completed treatment was significantly lower compared to those who did not complete, and treatment completers were more likely to be working at six months. With the exception of employment, the outcomes from the other sites were similar.

Although methadone, buprenorphine, and naltrexone adherence is associated with diminished risk of overdose death, it should be noted that discontinuing these medications increases the risk of overdose. There were no overdoses in the present study.

With regard to the ethical concerns surrounding naltrexone, all participants in this study were volunteers who could discontinue treatment at any time without affecting their treatment or criminal justice status. A symposium held by the University of Pennsylvania addressed the ethical issues of naltrexone being used with offenders in the criminal justice system.(38–40) Offering naltrexone treatment as an option met the test of ethical acceptability. It was even considered possible to offer naltrexone outpatient injections in lieu of incarceration during plea-bargaining.

There are limitations to the study that need to be addressed. One limitation of the study was the overall low follow-up rate of 66%, which varied considerably across sites, and the much lower follow-up rate for non-completers compared to completers. However, incarceration data were available for 74% of respondents. Moreover, when the data were re-analyzed and those who were lost to follow-up were considered treatment failures (e.g., opioid positive urine drug screen, incarcerated, and unemployed at six months), the difference between completers and non-completers was even more significant in terms of favoring the completer group. In these analyses, employment was significantly more likely in the completer group across all sites. The finding that individuals lost to follow-up tend to have worse outcomes than individuals who complete follow-up assessments has been demonstrated by other researchers for outcomes related to both substance abuse(41) and criminality.(42)

A second limitation was that we compared a three-month XR-NTX treatment protocol from one site with a six-month protocol from the other four sites. Analyses that included only participants from the four sites who received up to six injections showed similar results in opioid use and incarceration status at six months. Therefore, including those who only received up to three injections still showed an advantage for completers over non-completers at six months.

A third limitation was related to the statistical analyses. The statistical tests were bivariate with no control variable used in the analyses regarding outcomes. There were a large number of tests performed and some could be significant by chance.

A final study limitation was the lack of a comparison group. However, the purpose of this trial was to demonstrate the feasibility of treating opioid-dependent offenders and to provide pilot data for application of a larger randomized trial among the same five sites. This collaborative effectiveness trial was funded for five years and is currently underway. This study is evaluating the effectiveness and benefit-costs of six monthly injections of 380 mg of Vivitrol® brand XR-NTX plus treatment as usual (TAU) to TAU alone among a sample of 400 offenders over an 18-month evaluation period.

The findings from the current pilot study hold promise that XR-NTX may be a feasible and effective treatment option for opioid-dependent individuals who are under various levels of supervision by the criminal justice system across a range of treatment and geographical settings. While outcomes from the larger randomized effectiveness trial are certainly necessary, the findings from the pilot study may help to advance the awareness and potential adaptation of this medication within the criminal justice community.

Acknowledgments

The study was supported by grants from the National Institute on Drug Abuse (R01-DA-012268-05) and the Dana foundation.

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Table 1

Sample Characteristics (N=61)

Demographics	**%**	
Males	92	
Race		
Caucasian	51	
African American	28	
Hispanic	20	
Employed	33	
Married	15	
	Mean	**SD**
Average Age	37.5	9.8
Average Education	11.2	2.3
Drug Use	**Mean**	**SD**
Average years:		
Heroin	12.0	9.9
Other opiates	6.1	8.5
Cocaine	7.3	8.0
Alcohol	11.5	10.7
Prior drug treatments	6.9	6.8
HIV Risk Behaviors	**%**	
IV drug use	34	
Needle sharing	15	
No/inconsistent condom use	47	
Criminal Behavior	**%**	
Prior charges		
Drug charges	72	
Parole/probation violations	60	
Burglary, larceny, breaking & entering	42	
Assault	42	
Shoplifting/vandalism	38	
Robbery	33	
Weapons offenses	25	
Disorderly conduct	22	
Driving while intoxicated	15	
Forgery	12	
Contempt of court	10	
Homicide/manslaughter	5	
Prostitution	2	

Demographics	%	
	Mean	SD
Average # prior charges	13.1	14.8
Average incarcerations (months)	42.4	36.3

Table 2

Depot Naltrexone Injectionsby Site

	Number of Injections											
	1st		2nd		3rd		4th		5th		6th	
Site	**#**	**%**	**#**	**%**	**#**	**%**	**#**	**%**	**#**	**%**	**#**	**%**
University of Pennsylvania	35	100	28	80	22	63	20	57	18	51	16	46
New York University/Bellevue *	8	100	7	88	7	88	n/a	n/a	n/a	n/a	n/a	n/a
Rhode Island Hospital	7	100	4	57	2	29	2	29	2	29	1	14
Columbia University	7	100	7	100	5	71	2	29	2	29	2	29
Friends Research Institute/Baltimore	4	100	3	75	3	75	3	75	3	75	2	50
Total	**61**	**100%**	**49**	**80%**	**39**	**64%**	**27**	**51%**	**25**	**47%**	**21**	**40%**

* Received a total of 3 injections

Table 3

Treatment Completion and Six-Month Outcomes

Group	Injection Status	Completed 6 month follow-up	Urine positive for Opioids at 6 months	Any Incarcerations in past 6 months	Employed at 6 month follow-up
All Sites					
Completers (Received all monthly injections) †	28/61 (46%)	27/28 (96%)***	1/26 (4%)**	4/27 (15%)*	15/27 (56%)
Non-completers (Did not receive all monthly injections)	33/61 (54%)	13/33 (39%)	4/9 (44%)	9/18 (50%)	5/13 (39%)
Total	**61**	**40/61 (66%)**	**5/35 (14%)**	**13/45 (29%)**	**20/40 (50%)**
Penn Site					
Completers (Received all monthly injections)	16/35 (46%)	16/16 (100%)**	0/16 (0%)*	1/16 (6%)*	12/16 (75%)*
Non-completers (Did not receive all monthly injections)	19/35 (54%)	9/19 (47%)	2/6 (33%)	5/10 (50%)	3/9 (33%)
Total	**35**	**25/35 (71%)**	**2/22 (9%)**	**6/26 (23%)**	**15/25 (60%)**

†Total of 6 injections at Penn, Rhode Island, Columbia, Baltimore and 3 injections for NYU.

*$p < .05$

**$p < .01$

***$p < .001$