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Comparison of Clinical Trial Recruitment Populations: Treatment-Seeking Characteristics of Opioid-, Cocaine-, and Cannabis-Using Participants

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Abstract

This study examined the treatment history and intention to seek treatment among 489 individuals interested in substance use disorder clinical trial participation. Opioid and cocaine users were more likely than cannabis users to report having received treatment for substance use in the past, and more likely than cannabis users to report planning to seek treatment for substance use before exposure to recruitment advertising. Free cost was the aspect of clinical trial participation that most influenced the decision to make an intake evaluation appointment for opioid-dependent patients as compared to cocaine and cannabis-dependent participants, and the availability of individual psychotherapy most influenced those who were cannabis-dependent. Cannabis-dependent individuals evaluated for clinical trial participation reported that recruitment advertising was an important factor in leading them to seek treatment. These results have implications for clinical trial recruitment as well as public health efforts directed at encouraging cannabis-dependent individuals to seek treatment.

Keywords

Opioids; cannabis; cocaine; recruitment

INTRODUCTION

Most patients with substance use disorders are not receiving treatment (SAMHSA, 2009). Recruiting for clinical trial participation provides a unique opportunity to learn about the reasons why patients with substance use disorders choose to seek treatment. Clinical trial participants are recruited by a variety of methods, including paid advertising, public service announcements, and outreach to existing clinical treatment populations. Individuals receiving community-based treatment generally seek out or are referred to treatment providers based on clinical need. Since clinical trial recruitment utilizes methods that may in

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effect “create demand”, it is possible that these active methods of outreach affect treatment-seeking behavior in clinical trial participants. Knowledge gained about encouraging patients with substance use disorder to consider clinical trial participation may be relevant to public health efforts to encourage treatment seeking in general.

An important question is if there are substance-specific differences in treatment seeking behavior. Community-based treatment settings generally admit patients across substance use categories, while substance use disorder clinical trials typically focus on a single substance or substance class. Comparisons of the characteristics of participants presenting for evaluation for treatment trials across substance categories have been limited. McRae et al (2007), found that marijuana-dependent subjects were younger than cocaine-dependent subjects, more likely to be Caucasian, and completed more years of education. Marijuana-dependent subjects also reported significantly more days using than cocaine-dependent subjects, as well as higher levels of craving.

Given that there may be differences in the characteristics and treatment seeking-behaviors in different substance dependence classes, targeted and substance-specific methods may be necessary to promote treatment seeking or recruitment for clinical trial participation. Stephens et al (2004), reported on a brief intervention, the “Marijuana Check-Up”, for marijuana-dependent individuals who were experiencing adverse consequences from near-daily marijuana use, but were ambivalent about making changes. Piotrowski et al (1994), reported on the efficacy of six different recruitment strategies for a clinical trial of desipramine for the treatment of cocaine-dependent male veterans and found that using a hospital-based substance abuse inpatient unit was most effective at generating large numbers of potential subjects, while media-based strategies and community outreach were more effective at attracting cocaine users into treatment. Sayre et al (2004), reported on the recruitment and screening processes of outpatient substance abuse trials and found that callers referred by friends and family were more likely to be eligible than callers from other referral sources.

Treatment specific for cannabis use disorders is less available in the community as compared to treatment specific for cocaine or opioid use disorders. Research settings frequently offer types of treatment that are unavailable in community settings and research clinics may use different methods of recruitment than community programs. Clinical trial advertising that emphasizes unique or specialized treatment options may influence treatment-seeking behavior (i.e., advertising may act as an agent of change.) We hypothesized that as compared to cocaine- or opioid-using individuals responding to clinical trial advertising, those using cannabis would be: 1) less likely to report prior exposure to treatment services; 2) more likely to report consideration of treatment-initiation as a result of exposure to advertising and other recruitment methods; and 3) less likely to seek treatment at the urging of friends or family.

METHODS

Participants and Procedure

Participants were 489 individuals screened at a university-based treatment clinic for enrollment in a cannabis, cocaine, or opiate dependence pharmacotherapy clinical trial between October 2007 and November 2008. Participants were provided \$4 in reimbursement for transportation to attend the screening appointment. These individuals were asked to complete a survey designed to evaluate factors associated with clinical trial participation in substance use disorders. Recruitment methods for all trials were similar and consisted primarily of paid advertisements, Internet sources, and clinical referrals. Potential participants for all studies were initially screened over the telephone to determine general

eligibility. Inclusion criteria were reporting problems with substances presently or within the last month, willingness to undergo an evaluation, ability to give informed consent and to comply with study procedures, and being between 18 and 65 years of age. Individuals currently enrolled in a methadone maintenance program and those physically dependent on benzodiazepines were excluded. Research protocols were approved by the Institutional Review Board (IRB) of New York State Psychiatric Institute. All participants provided written informed consent prior to completing the survey and were provided with minimal reimbursement for travel expenditures.

Measures

Demographic information collected included age, gender, ethnicity, race, marital status, education, and employment. Attempts were made to locate missing demographic data by examining all screening records. The recruitment survey questionnaire was designed to evaluate the presence or absence of previous exposure to substance abuse treatment, assess whether participants were planning to pursue treatment prior to the time of advertisement exposure, and identify factors associated with the decision to schedule an initial screening appointment. Participants were asked to identify the primary substance use problem for which they were seeking treatment.

Data Analysis

Demographic characteristics, and treatment history and intention to seek treatment were compared across cannabis, cocaine, and opioid groups using ANOVA for continuous variables and Pearson's chi-squares for categorical variables. To assess the likelihood of treatment history and intention to treat across substance groups, logistic regressions were conducted on these two outcomes as a function of substance groups. Odds ratios (OR) and 95% confidence intervals were produced for the substance groups using cannabis group as the reference. All questionnaire responses were dichotomous (Y/N). The proportions of patients who answered yes to each statement were compared across substance groups using Pearson's chi-squares. Odds ratios and 95% confidence intervals were derived from logistic regressions to assess the likelihood of the respective questionnaire responses as a function of substance groups. All analyses were two-sided and conducted in SAS using a significance level of 0.05.

RESULTS

Substantial differences were found in participants' baseline demographics across the three substance groups. Table 1 reports the demographic characteristics, treatment history and intention to seek treatment across substance dependence classes. Cannabis-dependent participants were younger than cocaine- and opioid-dependent participants, and employed at a higher rate. There was a greater proportion of black participants in the cocaine-dependent group than the cannabis- and opioid-dependent groups. Opioid and cocaine users were more likely than cannabis users to report planning to seek treatment for substance use before learning about the availability of clinical trial participation [cocaine (OR=2.12, 95% CI: 1.35–3.32); opioid (OR=6.40, 95% CI: 3.46–11.84)], and having received treatment for substance use in the past [cocaine (OR=2.58, 95% CI: 1.65–4.03); opioid (OR=5.22, 95% CI: 3.14–8.67)].

Table 2 reports the factor that most influenced the decision to make an evaluation appointment among cannabis-, cocaine-, and opioid-dependent participants. Compared to cannabis users, cocaine and opioid users were more likely to view “consequences of substance use” as the biggest factor that influenced their decision to make an appointment for evaluation [cocaine (OR=1.93, 95% CI: 1.24–2.99); opioid (OR=2.21, 95% CI: 1.36–

3.58)]. Compared to opioid-dependent patients, cannabis-users were more likely to view “hearing or seeing advertisement” as the biggest factor that influenced their decision to make an appointment for an evaluation. Specifically, cannabis-dependent patients were 3.7 times (OR=3.74, 95% CI: 1.89–7.14) more likely to cite advertisement exposure as the factor that most influenced the decision to make an evaluation appointment than opioid-dependent patients.

Table 3 reports the aspect of research treatment that most influenced the decision to make an evaluation appointment. Compared to cannabis-dependent patients, opioid-dependent patients were more likely to view “free cost” as the most important factor (OR=2.22, 95% CI: 1.32–3.74) for making the evaluation appointment. Compared to cannabis-dependent patients, opioid-dependent patients were less likely to view “individual therapy” as the most important factor (OR=0.41, 95% CI: 0.20–0.86).

DISCUSSION

This study reports on some important differences among cannabis, cocaine, and opioid using individuals presenting for evaluation for substance use disorder clinical trials. Consistent with our hypothesis, cannabis using individuals had lower rates of past treatment and were less likely to be considering treatment at the time of exposure to clinical trial recruitment methods as compared to those with opioid or cocaine dependence. Also consistent with our hypothesis, a greater proportion of cannabis using participants reported advertising as the most important factor influencing their decision to seek treatment, as compared to those with opioid or cocaine dependence. The finding that friends and family are important sources of treatment-seeking recommendations and rates of these types of referrals were similar among cannabis, cocaine, and opioid using individuals, was did not support our hypothesis that social support for treatment seeking would be less important for cannabis users.

Since cannabis using individuals have lower rates of past treatment exposure, it may be that clinical trial recruitment advertising has a unique educational value for cannabis using individuals, informing them of the availability of cannabis-specific treatment. In this study, cannabis-dependent individuals were less likely to be planning to seek treatment as compared to cocaine- and opioid-dependent individuals. It may be that lack of awareness of treatment availability accounts for the lower rate of planned treatment seeking in the cannabis dependence group.

This study had several important limitations. The characteristics of the population recruited may not be generalizable to clinical trial participants in other geographical locations or by other recruitment methods. The survey administered to participants may not have captured important aspects of treatment-seeking behavior, such as specific events or circumstances that had a powerful effect on motivation to change their substance use patterns. The generalizability of these results obtained in a population responding to clinical trial advertisements to clinical settings is unknown. Selection factors for University-based clinical trial research participation are very likely to be different from the factors that drive community treatment seeking.

Recruitment strategies for cannabis use disorder clinical trials should take into account the treatment-naivete of this population by emphasizing the availability of cannabis-specific treatment. Based on the results of this study, individual therapy appears to appeal to cannabis-dependent treatment-seekers. Since the majority of patients with substance use disorder are not in treatment, strategies successful at recruiting patients for clinical trials may have value for community treatment settings. An often noted concern is that clinical trial participants are not representative of population of community treatment seekers.

However, Frewen et al (Frewen, Baillie et al. 2009), found that marijuana-dependent randomized controlled trial participants were representative of treatment seekers, suggesting that methods of recruitment for clinical trial participants may be applicable for community treatment programs.

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Table 1
Demographic characteristics, treatment history and intention to seek treatment across substance dependence classes

	Cannabis (N=148)		Cocaine (N=202)		Opioid (N=139)		Statistics	P value
	Mean (SD)	n (%)	Mean (SD)	n (%)	Mean (SD)	n (%)		
Age	35.8 (10.8)		42.2 (8.5)		40.1 (10.3)		F _{2,472}	<0.0001
Gender							X ²	
Male	111 (77.6)		153 (78.1)		103 (75.2)		0.4 ^a	0.81
Race								
Black	35 (24.8)		73 (37.4)		25 (18.5)		23.0 ^b	0.0008
White	67 (47.5)		67 (34.4)		67 (49.6)			
Hispanic	21 (14.9)		41 (21.0)		33 (24.4)			
Others	18 (12.8)		14 (7.2)		10 (7.4)			
Education								
Some college or above	98 (75.4)		99 (53.5)		66 (54.1)		17.9 ^a	<0.0001
Married	33 (24.8)		36 (19.4)		19 (15.7)		3.4 ^a	0.19
Employed	84 (63.6)		108 (57.1)		55 (45.1)		9.1 ^a	0.01
History of Past Treatment	46 (31.5)		109 (54.5)		97 (70.8)		43.8 ^a	<0.0001
Planned to Seek Treatment Prior to Recruitment	78 (54.2)		140 (71.4)		121 (88.3)		39.9 ^a	<0.0001

Denominators may differ because of missing data

^a df=2

^b df=6

Table 2

Factor that most influenced decision to make evaluation appointment

	Consequences of substance use		Hearing or seeing advertisement		Recommendation of employer [†]		Recommendation of friend or family member		Other		
	N	n (%)	OR (95%CI)	n (%)	OR (95%CI)	n (%)	OR (95%CI)	n (%)	OR (95%CI)	n (%)	OR (95%CI)
Cannabis	148	71 (48.6)	1.00	41 (28.1)	1.00	0 (0)	-	21 (14.4)	1.00	23 (15.8)	1.00
Cocaine	202	124 (64.6)	1.93 (1.24–2.99)	24 (12.5)	0.37 (0.21–0.64)	3 (1.6)	-	38 (19.8)	1.47 (0.82–2.63)	12 (6.3)	0.36 (0.17–0.74)
Opioid	139	92 (67.7)	2.21 (1.36–3.58)	13 (9.6)	0.27 (0.14–0.53)	1 (0.7)	-	19 (14.0)	0.97 (0.50–1.89)	20 (14.7)	0.92 (0.48–1.77)

* Bolded values indicate statistical significance at alpha=.05.

[†] Odds ratios cannot be computed due to zero cell count.

Table 3

Aspect of research treatment that most influenced decision to make evaluation appointment

N	Free Cost		Individual Therapy		Availability of treatment not offered elsewhere		University Affiliation		Convenient Locations		Reimbursement for travel expenditures		Opportunity for research study participation	
	n (%)	OR (95%CI)	n (%)	OR (95%CI)	n (%)	OR (95%CI)	n (%)	OR (95%CI)	n (%)	OR (95%CI)	n (%)	OR (95%CI)	n (%)	OR (95%CI)
Cannabis	148	1.00	34 (24.8)	1.00	27 (19.7)	1.00	36 (26.3)	1.00	31 (22.6)	1.00	5 (3.7)	1.00	28 (20.4)	1.00
Cocaine	202	1.38 (0.84–2.28)	56 (31.3)	0.79 (0.44–1.41)	29 (16.2)	0.79 (0.44–1.41)	50 (27.9)	0.86 (0.50–1.48)	36 (20.1)	1.48 (0.61–3.59)	12 (6.7)	1.90 (0.62–5.51)	48 (26.8)	1.43 (0.84–2.43)
Opioid	139	2.22 (1.32–3.74)	55 (42.3)	0.41 (0.20–0.86)	12 (9.2)	0.41 (0.20–0.86)	33 (25.4)	0.98 (0.55–1.75)	29 (22.3)	0.51 (0.15–1.74)	5 (3.9)	1.06 (0.30–3.74)	27 (20.8)	1.02 (0.56–1.85)

* Bolded values indicate statistical significance at alpha=0.05.