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Journal of Substance Abuse Treatment 33 (2007) 355–361

Journal of Substance Abuse Treatment

Regular article

Comparison of demographic and clinical characteristics between opioid-dependent individuals admitted to a community-based treatment setting and those enrolled in a research-based treatment setting

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Received 23 October 2006; received in revised form 13 November 2006; accepted 25 December 2006

Abstract

Despite the significant developments in pharmacotherapy and behavioral treatments for addiction, the dissemination of new treatment methods into the community has been slow. It has been pointed out that treatments developed in research settings may be impractical in community treatment settings, which might help explain the transition lag. Screening and recruitment of participants for research studies might partially explain this, as there is evidence that substance-abusing individuals who participate in clinical research are different on a number of measures from treatment seekers. However, no study has directly compared treatment seekers with research participants drawn from similar populations using prospective methods. This study compared the demographic characteristics, drug use and psychosocial problem severity levels, and personality traits of opioid-dependent individuals seeking help in a community setting (n = 502) with those of opioid-dependent individuals in a primarily research-based drug abuse treatment setting (n = 459); both settings offered a similar set of treatment services (opioid agonist medication and counseling). Although the overall findings revealed numerous similarities between the groups, differences were also observed. Most notably, there were significantly fewer women in the research sample than in the community-based treatment sample. Other differences included a modest but statistically significant increase in psychosocial problem severity levels in the community-based treatment sample and higher drug use problem severity levels in the research sample. Interestingly, many of these differences were strongest in women as compared with men.

Keywords: Methadone; Substance abuse; Opioid abuse; Clinical research

1. Introduction

Many novel pharmacologic and behavioral treatments for drug addiction have been tested in multiple research programs over the past few decades (Carroll, Sinha, Nich, Babuscio, & Rounsaville, 2002; Chutuape, Silverman, & Stitzer, 1999; Eissenberg et al., 1997; Foster, Brewer, & Steele, 2003; Griffith, Rowan-Szal, Roark, & Simpson, 2000; Jones et al., 1998; Kakko, Svanborg, Kreek, & Heilig, 2003; Pani, Maremmani, Pirastu, Tagliamonte, & Gessa, 2000), yet broad dissemination and implementation of these advances in community-based settings lag behind research findings (Institute of Medicine, 1998). A number of interrelated issues contribute to this ongoing challenge (Institute of Medicine, 1998; Russell & Orlinsky, 1996; Seligman, 1995; Strain & Stitzer, 1999). Among them are concerns that participants in research settings may differ in important ways from those seeking care in community-based sites and that these differences may confound the effects of experimental interventions (McKay et al., 1998) and limit the generalizability of results to nonresearch facilities.

Some results from this study were presented at the 2004 Annual Meeting of the College on Problems of Drug Dependence.

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0740-5472/07/$ – see front matter
doi:10.1016/j.jsat.2006.12.014

Differences between research and publicly funded community-based treatment programs in recruiting practices and eligibility criteria may affect the demographic and psychiatric characteristics of patients who choose to enroll at these facilities. For instance, research-based settings often attract participants through mixed media advertisements (Krupnick, Shea, & Elkin, 1986) that describe general inclusion criteria and offer financial compensation, whereas the advertising practices of publicly supported community-based clinics are usually less extensive. In addition, research-based programs often use screening procedures that are narrowly defined by specific study protocols, whereas community-based programs use more inclusive eligibility criteria.

No study has prospectively compared the characteristics of substance-using individuals enrolled in a research setting with those of substance-using individuals admitted to a community-based setting. Studies that have used alternative methodologies provided some evidence that individuals who enroll in research settings differ from clinical populations. Humphreys and Weisner (2000), for instance, used exclusion criteria common to studies on alcohol problems to categorize individuals seeking community-based treatment for an alcohol use disorder as eligible or ineligible for research participation. These criteria produced a predominantly Caucasian research-eligible sample with comparatively greater financial resources and lower psychiatric, medical, and other psychosocial severity levels. Carroll, Nich, McLellan, McKay, and Rounsaville (1999) compared participants enrolled in two clinical trials for cocaine dependence (Carroll, Nich, Ball, McCance, & Rounsavile, 1998; Carroll et al., 1994) with those in community-based cocaine and alcohol abuse treatment programs (McLellan et al., 1994). The results dovetailed with those observed by Humphreys and Weisner in that the research participants were more likely to be Caucasian and relied less on public assistance. The research participants also were more educated and reported greater use of cocaine and other drugs.

The methods used by these studies possess both strengths and limitations. Each study was retrospective and used large samples, enhancing the likelihood of detecting between-group differences. The study by Humphreys and Weisner (2000) relied on an analogue design that may not represent the combined and interactive effects of recruitment and screening, whereas that by Carroll et al. (1999) may have been confounded by the use of comparison groups that were recruited and examined at different locations and times.

This study addressed these concerns by using a prospective design to evaluate individuals admitted to a primarily research-oriented drug abuse treatment clinic (Behavioral Pharmacology Research Unit [BPRU]) and those admitted to a primarily community-based treatment clinic (Addiction Treatment Services [ATS]). These two programs are located within the Johns Hopkins Bayview Medical Center campus, draw from similar communities, and use similar treatment approaches (opioid agonist medication and counseling). The participants from both programs were compared on demographic characteristics and multidimensional measures of problem severity and psychologic traits.

2. Materials and methods

2.1. Participants

Participants represented 961 admissions to opioid agonist treatment from April 1984 through February 1998. All participants met *Diagnostic and Statistical Manual of Mental Disorders, Revised Third Edition* criteria for opioid dependence as well as Food and Drug Administration requirements for treatment with opioid agonist medications. They were paid between $30.00 and $40.00 for completing the intake assessment measures (higher reimbursement rates were used during the subsequent years of the study). All data were collected as part of a long-term study on the demographic, drug use, personality, and psychosocial characteristics of treatment-seeking opioid-dependent individuals. The study was reviewed and approved by the Johns Hopkins Institutional Review Board for research with human subjects.

2.2. Treatment settings and recruitment as well as screening procedures

Participants represented consecutive admissions to a series of outpatient treatment studies that were conducted between 1984 and 1998; participants in these primary studies also provided informed written consent to participate in our study. They sought admission either to the ATS or to the BPRU.

2.2.1. The BPRU program

The BPRU is a research-based program that maintains an outpatient clinic supporting both behavioral and pharmacology studies on dependence on opioids and other drugs. It actively recruits research participants through advertisements in local papers and other media. The BPRU admission process used a preadmission assessment and screening as well as a final assessment (including a medical assessment and physical examination) at the time of participants' admission. Major exclusion criteria were (1) having a significant psychiatric illness (e.g., schizophrenia), (2) having a significant medical problem (e.g., diabetes), (3) having a cognitive impairment that would impede ability to consent or participate, and (4) being pregnant. Medical exclusions were based on the judgment of the medical staff in the program based on each potential participant's history, physical examination findings, and routine laboratory work results. Admission and opioid