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Methods of Recruiting Adolescents with Psychiatric and Substance Use Disorders for a Clinical Trial

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Abstract

Background—The present paper reports on recruiting strategies in a 16-week, multi-site trial of osmotic-release methylphenidate combined with cognitive-behavioral therapy in adolescents with co-occurring attention deficit hyperactivity disorder and substance use disorder.

Methods—A multifaceted recruiting strategy was employed that targeted multiple referral sources, used incentives, involved numerous staff members, emphasized the therapeutic alliance during prescreening, and utilized data to modify strategies based on results. Overall, 303 adolescents were randomized from 1333 total referrals across 11 participating sites.

Results—Overall, existing treatment program sources, including treatment program staff, social services, the juvenile justice system, and mental health clinics provided a majority of referrals for pre-screening and randomization.

Conclusions and Scientific Significance—These results support the feasibility of recruiting dually-diagnosed adolescents utilizing a multifaceted approach involving the entire study team.

Introduction

A lack of research on effective ways of recruiting adolescents with co-occurring psychiatric and substance use disorders (SUDs) has contributed to the paucity of clinical trials and significant research gaps in such youths (1). Development of feasible and effective methods of recruitment is critical to trial performance. Poor recruitment can lead to prohibitive costs, inadequate statistical power, and reduced scientific value of clinical trials (2).

Several clinical characteristics of adolescents with co-occurring psychiatric disorders and SUDs pose significant intrinsic challenges to successful recruitment. These include poor motivation for SUD and mental health treatment (3), mistrust of researchers (4, 5), and dependence on parents for consent and transportation to treatment (4). Adolescents' status as a vulnerable population raises other issues related to recruitment, including the need for additional safeguards against coercive study participation, as well as ethical and legal considerations such as the protection of confidentiality.

*Drs. Bailey and Jaffee shared equally in the authorship of this manuscript.

Declaration of Interest

Dr. Weiss receives research grant support from NIDA and Eli Lilly and Co., Inc. and has consulted to Titan Pharmaceuticals, Inc.; Dr. Riggs receives research grant support from NIDA, receives active medication and matching placebo for the CTN OROS-MPH multi-site trial from McNeil, and serves on the scientific advisory board for Shire; Dr. Bailey has been on the speaker's bureau of Forest Pharmaceuticals and Pfizer and has received research support from Titan Pharmaceuticals, Inc.

Dr. Jaffee, Ms. Lohman, and Ms. McDonald report no conflicts of interest.

Portions of these data have been presented at the following meetings: The 70th annual meeting of the College on Problems of Drug Dependence, June 14–19, 2008, San Juan, PR, and the 55th annual meeting of the American Academy of Child and Adolescent Psychiatry, October 28 – November 2, 2008, Chicago, IL.

The literature on clinical trials for adolescents with co-occurring psychiatric and substance use disorders is sparse, and descriptions of recruiting strategies are typically limited to summaries within “methods” sections of these publications. We are aware of no literature that specifically focuses on recruiting methods and the outcome of those methods in clinical trials for adolescents with these co-occurring disorders. Our search of this topic, using PubMed and PsychInfo databases and the keywords “recruiting/recruitment/recruit,” “adolescents/children,” “psychiatric disorders,” and “substance use/abuse/dependence” did not identify any published papers reporting in detail on recruiting methods for clinical trials involving these adolescents. We did, however, identify three published papers that report in detail on recruiting methods and the outcome of those methods for clinical trials involving adolescents having *either* a psychiatric disorder or SUD(6–8). This literature highlights the difficulty that can be encountered in recruiting adolescents, the importance of incentives, and the importance of using a multifaceted approach to recruiting. It is unclear whether methods used to successfully recruit adolescents with either psychiatric disorder or SUD are generalizable to recruiting adolescents with both disorders.

To address the current research gap on methods of recruiting dually diagnosed adolescents for clinical trial participation, we report on methods used to recruit 303 participants for a 16-week, multi-site randomized controlled trial of osmotic-release methylphenidate (OROS-MPH) plus cognitive-behavioral therapy for attention deficit hyperactivity disorder (ADHD) and SUD. This study – the largest multi-site controlled trial to date combining pharmacotherapy with psychotherapy for adolescents with co-occurring psychiatric disorders and SUDs – was sponsored by the National Institute on Drug Abuse (NIDA) Clinical Trials Network (CTN).

Methods

Study Design and Participants

This study was conducted at 11 community-based adolescent substance treatment centers affiliated with the NIDA CTN throughout the United States; all sites obtained Institutional Review Board (IRB) approval from their respective institutions. The study also included a Clinical Coordinating Center, a Data and Statistics Center, collaboration with NIDA personnel, and monitoring by a Data Safety and Monitoring Board. The first 3 sites began enrolling participants in April, 2006. The remaining 8 sites initiated enrollment between July, 2006 and March, 2007. Recruitment ended in June, 2008 after the targeted enrollment of 300 participants had been achieved; the final study sample was 303.

Participants were adolescents aged 13 – 18 who 1) met DSM-IV criteria for ADHD, 2) had at least one non-nicotine SUD, and 3) reported substance use in the past month. Adolescents with current opioid dependence or methamphetamine abuse or dependence were excluded. Participants were randomized to 16 weeks of either OROS-MPH or placebo and also received 16 weeks of cognitive-behavioral therapy targeting their substance use at no cost. Participants were paid \$50 for completing baseline screening, \$25 for each weekly follow-up visit attended, and \$30 for the final week-16 assessment, plus an additional \$5 for returning the completed medication diary and pill bottle at study completion (maximum=\$485).

Recruitment Methods and Referral Sources

We report on referral source data for 1,333 adolescents who completed telephone pre-screening, of who 449 gave written informed consent for baseline assessment, and 303 were randomized.

Consistent with the CTN mission of reaching patients in the community-based settings where most treatment is provided (9), this study by design did not rely heavily on media advertising for recruiting. Instead, referral networks were developed from existing community treatment program (CTP) sources, including 1) treatment program staff, 2) social services, 3) the juvenile justice system (4) juvenile diversion agencies, 5) drug court and judges, and 6) mental health clinics. Additionally, new community-based referral networks were developed through study staff outreach to 1) staff at local area schools, and 2) medical clinics. New referral sources were also fostered by having study staff give presentations to other community-based organizations. Radio, television, and newspaper advertising were also used to recruit study participants. These were supplemented by bus posters, online postings, and distribution of fliers and brochures at various locations in the community. Some sites obtained IRB approval to utilize respondent-driven sampling procedures, in which small incentives (\$5–\$10) were provided to study participants who made referrals (10). All sites were encouraged to involve multiple staff members in the recruiting process rather than assign this responsibility to any single individual.

Measures and Documentation of Referral Source

Referral sources for potential participants were systematically tracked by all sites using a standardized Screening and Progress Log. This log was used to document referral source and to track adolescents (and their parents or guardians) through the processes of telephone pre-screening, consent, baseline screening, and randomization. Screening and Progress Log data were reviewed weekly by the lead research team and followed by telephone consultation with participating CTP study staff. The lead team provided site-specific feedback about recruitment and referral trends and methods, and worked collaboratively with CTP staff to refine recruitment efforts.

Screening Procedures

Telephone pre-screening and baseline in-person screening procedures were designed to foster the establishment of an initial therapeutic alliance. Potential participants and/or their parents contacted the clinic study staff by telephone and were provided with detailed information about the study, including requirements of participation and eligibility, confidentiality parameters, incentives, and treatment. If preliminary eligibility requirements were met on telephone pre-screening, interested adolescents and their parents or guardians were invited to come to the clinic to provide informed consent and participate in more extensive baseline screening to determine study eligibility.

Results

Referral sources for those completing telephone pre-screening and randomization are reported in Table 1. Overall, existing treatment program sources, including treatment program staff, social services, the juvenile justice system, and mental health clinics provided a majority of referrals for pre-screening ($n=811$, 61% of all pre-screened individuals) and randomization ($n=198$, 65% of all randomized participants). As a category, new community outreach efforts provided the second greatest number of referrals for prescreening ($n=281$, 21%) and randomizations ($n=69$, 21%). As a category, media-based efforts provided the smallest number of referrals ($n=237$, 18%) and randomizations ($n=35$, 12%). Combined, non-media sources accounted for 82% of all referrals for pre-screening and 88% of randomized participants.

Existing referral sources and new community outreach efforts exhibited similar rates of randomizing potential participants who were pre-screened: 24% and 25%, respectively. Media-based efforts resulted in a 15% rate of randomization for potential participants who

were pre-screened. Chi-square tests performed on these results indicate a statistically significant difference between the randomization rates for existing referral sources compared to media-based efforts $\chi^2(1, N=518) = 7.68, p < .01$, and for community outreach efforts compared to media-based efforts $\chi^2(1, N=1,048) = 9.87, p < .01$.

Discussion

Our results support the feasibility of recruiting dually-diagnosed adolescents for participation in controlled clinical trials, using the recruitment methods reported. During the total enrollment period of 26 months, 11 sites conducted 1,333 pre-screening evaluations and 449 baseline assessments and randomized 303 participants to this 16-week trial.

These results also highlight the importance of recruiting from existing treatment program referral networks and of developing new referral networks through community outreach efforts: in the present study, 88% of randomized participants were referred from these sources. It is also noteworthy that we achieved our recruiting target of randomizing over 300 participants without a major emphasis on media advertising, which accounted for only 12% of randomized participants. The fact that a majority of referrals came from existing networks and community outreach efforts may increase the generalizability of this study's primary outcome results, since controversy exist regarding whether participants recruited via media sources are different from those entering treatment programs (11).

Similarly, existing referral sources and community outreach efforts demonstrated rates of randomization for potential participants who were pre-screened that were significantly higher than the rates for media advertising.

In addition to the aforementioned efforts at generating referrals, two other elements appear to have been important in our recruitment methods. First, close monitoring and systematic evaluation of referral, screening, and enrollment logs was followed by site-specific feedback to refine and target the most effective recruitment methods. Regular systematic monitoring and feedback may have been important in reinforcing site recruitment efforts. Second, our pre-screening evaluation was designed to establish an initial therapeutic alliance by thoroughly explaining study goals and requirements of participation, emphasizing confidentiality, and providing an opportunity for potential participants and their parents or guardians to address any questions they had about the study.

These findings are consistent with work cited earlier, which emphasized the use of incentives, involved the entire research team in recruiting efforts, engaged multiple referral sources including schools and trusted others, and systematically monitored and modified recruiting strategies (8, 12). Moreover, the rates of randomization to this study are within the range of randomization rates observed in other studies in recruiting adolescents for clinical trial participation (12, 13).

Limitations

An important limitation is that the costs associated with different recruiting methods were not tracked systematically. Thus, we are unable to make statements about the relative efficiency of different recruiting methods used. Future studies should track staff time and specific costs associated with recruitment by referral source to further improve recruitment methods for adolescent clinical trials. Additionally, the tracking methods employed in the present study do not permit us to more precisely determine the number of participants referred and enrolled from specific subcategories of existing CTP referral sources (e.g., juvenile justice, social services); participants were often admitted or registered as clinic patients regardless of the outside referral source prior to internal referral to study staff. In

such cases, the study referral source was labeled as a referral from within the CTP rather than from the source initially referring the patient to the clinic. Additional research is warranted to evaluate whether the type of treatment, the establishment of new referral sources to augment existing clinic sources, or other factors are important contributors to the successful recruitment of adolescents for research studies.

The results of this study demonstrate the feasibility of recruiting dually-diagnosed adolescents for clinical trials. These results may be useful to future clinical trials research of adolescents with co-occurring psychiatric disorders and SUDs, which will help to fill significant gaps in the empirical literature on treatments for these individuals.

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Table 1

Number of referrals and randomized participants by referral source

Referral Source	Prescreened <i>n</i> (%)	Randomized <i>n</i> (%)
Existing Treatment Program Sources		
Within-Program, Juvenile Justice, Social Services, Other Mental Health Clinics	811 (61)	198 (65)
Community Outreach Efforts		
Schools	140	27
Parent/Relative/Friend/Acquaintance	111	33
Primary Care/Medical Clinic	24	5
University Email	6	4
Total Community Outreach	281 (21)	69 (23)
Media-Based Efforts		
Bus Posters	33	5
Flyer/Brochure/Poster	68	3
Newspaper Advertising	59	20
Television Advertising	10	3
Radio Advertising	63	3
Online Advertising	4	1
Total Media	237 (18)	35 (12)
Unknown	4 (<1)	1 (<1)
Total Overall	1,333 (100)	303 (100)

Key: Percentages (%) represent percent of total *n* prescreened and randomized