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Implementing substance abuse group therapy clinical trials in real-world settings: Challenges and strategies for participant recruitment and therapist training in the Women's Recovery Group Study

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Abstract

Background and Objectives—Open-enrollment group therapy research is challenged by the participant recruitment necessary to ensure continuous group enrollment. We present successful strategies to overcome the following barriers during the Women's Recovery Group (WRG) two-site clinical trial (N = 158): maintenance of sample size and balanced gender randomization during continuous enrollment, maintenance of group attendance, and training and retention of therapists over the 24-month continuous group enrollment.

Methods—To increase recruitment, we targeted referral sources yielding the highest enrollment conversion at each site. Group sessions were consistently held regardless of group size. Therapists were trained in two teams allowing for coverage and uninterrupted treatment over 24 months.

Results—At both sites recruitment and enrollment increased with each successive quarter. Sample size and end date targets were met without disruptions in treatment. Group therapists reported high satisfaction with their training and treatment experiences.

Discussion and Conclusions—Strategies implemented supported targeted enrollment and study duration, stability of open enrollment group therapy frame, and therapist retention and satisfaction.

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Background and Objectives

The need to develop treatments that can be implemented in "real world" settings has been widely acknowledged,[1] yet the gap between treatment delivered in community programs and empirically-validated treatment persists.[2,3] Although most behavioral treatments for substance use disorders (SUDs) in the community are administered in groups, few studies examine the efficacy of group therapy for SUDs,[3] and those that do examine treatment in "closed" groups (i.e., all members start and end together).[3] However, in clinical practice, group therapy typically takes place in an "open" or "rolling" format,[4] where group members join at different times and membership is fluid. Implementing clinical trials of open-enrollment group therapy presents a number of challenges,[3,5–7] such as sustained recruitment,[6] retention, and randomization, which are necessary to ensure that groups remain open and continue to "roll." Any fall-off in recruitment can lead to inadequately populated groups and risks disrupting treatment.

In addition to the standard challenges of adequate clinician training and preventing clinician turnover,[8–16] open enrollment group therapy studies face another challenge to therapist retention. While closed group studies may allow therapists to plan absences between group sequences, open-enrollment groups do not offer these opportunities. Although there are examples of successful implementations of open-enrollment SUD group therapy trials,[12,17] including one paper identifying site differences in participant retention,[17] we could not identify published articles describing solutions to participant recruitment and retention, and therapist training challenges for these trials. In a small Stage I behavioral therapy developmental trial, we demonstrated efficacy of the women-focused, single-gender Women's Recovery Group (WRG) compared with standard mixed-gender Group Drug Counseling (GDC).[18] In this pilot study, the groups were implemented in semi-open format with continuous enrollment into the groups for the first several weeks until the requisite number of participants were enrolled. Groups then continued for 12 additional weeks until all subjects completed the sequence and then the group concluded. The WRG model is intended to be an "off-the-shelf" group therapy, ready for immediate dissemination into practice if demonstrated to be effective. Based on the Stage I pilot study,[18] a larger two-site effectiveness trial was designed to approximate clinical practice, including administering groups in an open-enrollment format. This article describes the implementation challenges in the two-site, Stage II clinical trial comparing the new manual-based, group treatment for women with SUDs (WRG) with mixed-gender GDC. We describe effective strategies developed to address the challenges of implementing this group therapy trial with continuous, open enrollment throughout the 24-month recruitment period.

Methods

Overview of the Trial

This Stage II study was conducted in outpatient clinics at an academic hospital (McLean Hospital, Belmont, MA) and a community treatment program (SSTAR: Stanley Street Treatment and Resources, Fall River, MA). The protocol was approved by the McLean Hospital Institutional Review Board, and written informed consent was obtained. Included

participants a) were at least 18 years of age, b) met current DSM-IV criteria for substance dependence for at least one substance besides nicotine, c) used substances at least once within the past 60 days, d) planned to be available for follow-up in-person or by telephone, e) consented for study personnel to communicate with other mental health professionals from whom they were receiving care, f) furnished the names of two people who could assist in locating them, g) were interested in group treatment, and h) were able to attend weekly groups. Exclusion criteria included: a) a current medical condition preventing regular group attendance, b) mental retardation or an organic mental disorder, c) diagnosis of a psychotic disorder or bipolar I disorder, d) currently in residential treatment, e) need for medical detoxification (however, these participants could enter the study after medical detoxification), f) current intravenous drug use, and g) manifestation of self-injurious or other behaviors that would interfere with group participation.

Participants who expressed interest in the study completed a 20-minute pre-screen with a research assistant (RA). Participants meeting pre-screen criteria were invited to complete a comprehensive baseline assessment. Eligible women were randomly assigned to the experimental condition (WRG) or control condition (GDC). Men were assigned to GDC. In order to keep group sizes approximately equivalent and have equal numbers of women randomized to WRG and GDC, it was necessary to run two GDC groups at each site. Both treatments consisted of twelve, 90-minute weekly sessions. During these 12 weeks, participants could attend other outpatient treatment, with the exception of another clinician-led group therapy focused on SUDs. Follow-up assessments were conducted at months 1–6, and six months post-treatment (Month 9). Participants were compensated for research assessments, but not for attending groups. The intent-to-treat sample was 52 and 48 women randomized to WRG and GDC, respectively, and 58 men assigned to GDC. The mean age was 47.0 years (SD = 1.0), 94.3% were White, and 4.4% African American. Seven percent did not graduate from high school, 18.4% earned a high school degree, 20.9% attended some college, and 53.8% had a college degree or higher. Thirty-eight percent were married, 26.6% had never married, and 21.5% were divorced. Forty-three percent were not employed, 32.9% were employed full- or part-time, 13.3% were disabled, and 6.3% were retired. Alcohol dependence was the most prevalent SUD diagnosis (88.6%), followed by cocaine dependence (17.7%), cannabis dependence (12.0%), opioid dependence (16.5%), and sedative dependence (10.1%). The majority of the sample had another co-occurring Axis I (73.4%) or Axis II (15.2%) disorder.

Recruitment Strategies

Referral Sources

Examination of referral sources: We initially pursued potential referral sources from clinicians within host treatment programs, private practices, and other area treatment programs; posted flyers in host programs, local community centers, and sites for self-help meetings; placed advertisements on craigslist, in newspapers, and on the radio.

Over time, we observed that certain referral sources were consuming disproportionate resources relative to the number enrolled subjects. Therefore, we evaluated referral sources to identify the most effective (see Figures 1 and 2). Newspaper ads resulted in 24.5% of all

pre-screened individuals, but only 14% of enrolled participants. Participants referred from in-house programs and clinicians resulted in 48.7% of those pre-screened, and 69.8% of the enrolled sample. Thus, we prioritized activities related to facilitating in-house referrals over other, less effective recruitment strategies.

Addressing clinician barriers to referrals: Staff attitudes toward research can influence recruitment in clinical trials.[19] Clinical staff may be reluctant to refer to clinical trials because they do not believe the study treatment will improve outcome, are skeptical of scientific research, or believe it will result in a reduction in income by diverting referrals.[15,20–22] Despite previous experience with research protocols at both sites,[18,23–25] we noted two main obstacles to clinician referrals to our study: a) reluctance to refer and b) forgetting to refer potentially eligible subjects. We explained to clinical staff that the study's group therapies were active treatments and that study participants could continue in most other treatment, including individual therapy and pharmacotherapy. In addition, we implemented strategies to help clinicians remember the study: posting signs with abbreviated eligibility criteria and staff contact information in clinician lounges, sending reminder letters and emails to clinicians, and distributing business cards with staff contact information and key points about the study. Additionally, we gave clinicians mugs monogrammed with "Recovery Group Study" to thank them for referrals and provide a visual reminder to continue referring. RAs maintained regular contact and forged strong interpersonal connections with clinical staff. In-house clinicians were encouraged to introduce interested patients to RAs for screening and study information. RAs consistently attended weekly rounds to help staff identify appropriate referrals, and consulted regularly with program staff.

Adequate Research Staffing for Participant Recruitment and Assessment— Recruiting for this open-enrollment group therapy study was time-intensive. Baseline assessments required five to eight hours, and recruitment demanded more time than anticipated. The initial staffing plan of one RA per study site was insufficient. Re-allocation of staff time at one site and hiring an additional RA at the second provided two RAs per site for most of the recruitment and enrollment period.

Modifying Inclusion/Exclusion Criteria to Enhance Recruitment—Inclusion/exclusion criteria permitted medical detoxification for potentially eligible participants prior to study entry, but many self-referred individuals did not pursue recommended medical treatment. Recruitment procedures were modified to offer referrals to detoxification programs at the pre-screen level (rather than after completion of a baseline assessment). These individuals were asked to contact an RA following medical detoxification. This resulted in enrollment of several eligible participants and saved considerable time by eliminating baseline assessments of those who did not ultimately follow through with treatment.

We amended two exclusion criteria within the first two months of recruitment. We initially required individuals to remain in the geographical area during the entire study period. These individuals were not excluded if requisite follow-up assessments could be completed by

telephone. We also eliminated the upper age limit of 65 years as it excluded otherwise eligible participants and decreased the generalizability of the sample.

Retention

Participant Retention during Baseline Assessment—Retaining participants through the baseline assessment was challenging. Successful strategies to advance participants through the assessment process quickly and efficiently varied by site. At both sites, offering lunch to participants to complete the assessment in one day was effective. At SSTAR, participants unable to complete the assessment in one day were offered movie tickets if they could complete it within the same week. At McLean, RA flexibility to schedule assessments early in the morning or at the end of the workday was effective. At McLean, for participants who opted to complete the baseline assessment over the course of more than one day, scheduling both appointments ahead of time proved effective for timely completion, while at SSTAR this was impractical, as participants were often unable to predict their availability in advance.

Participant Retention between Baseline Assessment and Enrollment in Group —Wait-time between the initial clinical assessment and first treatment session is negatively correlated with the likelihood of substance dependent patients attending subsequent treatment sessions.[26] In our study, the critical time between participant completion of the baseline assessment and enrollment in group treatment consisted of two periods: a) between assessment and group assignment, and b) between group assignment and joining group. Separate strategies were used to minimize time participants spent in each waiting period. We implemented an “express review” in which the project manager and principal investigator (PI) discussed participants’ eligibility immediately following baseline completion, rather than waiting to review with the whole team. Randomization and enrollment could often take place within a day after assessment completion. For randomized participants who were placed “on hold” to start group (e.g., because a group briefly stopped rolling or because of a gender imbalance in the available GDC group), RAs maintained regular phone contact. This period was a time of high risk for losing eligible participants due to loss of interest in the study or relapse. Therefore, we amended our procedures to start the group with as few as two participants (rather than waiting for three or four members).

Maintaining Group Attendance—Continuity of weekly rolling group attendance was threatened when few participants attended in a given week. All participants attended a pre-group meeting with the therapist, who reviewed group rules and highlighted the importance of group attendance. However, even when six to eight participants were enrolled in a group, only one to three participants might attend on a particular day. To address this problem, RAs made reminder calls the day before and/or the day of group. At SSTAR, RAs tried to schedule follow-up appointments (for which participants were compensated) on the same day as group. Where possible, we offered taxi vouchers to facilitate attendance. Initially, if only one participant could attend group, our policy was to cancel. However, this practice discouraged participants who were available to attend. Thus, we modified our policy and held an abbreviated, 60-minute session with a single participant. This is similar to clinical practice in which a clinician might meet individually with a patient who came to a scheduled

group but was the lone attendee. This practice seemed to "hold" the participant in the treatment trial until they were re-joined by other participants. Although smaller groups sometimes disappointed participants, RAs and therapists framed it as an opportunity to share information they may have felt less comfortable sharing in a larger group.

Therapist Training and Transition

In order to recruit our target sample size, we estimated that groups would need to run in an open-enrollment format for approximately 24 months. Given that long studies often have therapist attrition,[8] we asked for study therapists to commit to 12 months. Due to cost and efficiency concerns, we provided training for all study therapists at the outset of the trial. Thus, we recruited eight therapists who were divided into two "teams." Team 1 therapists conducted groups during months 1–12 and Team 2 therapists during months 13–24. Each team consisted of one GDC and one WRG therapist for each study site. In addition to helping with therapist attrition, implementing therapist transition decreased the chance that differences in outcomes between the two conditions would be associated with therapist effects. It also demonstrated that multiple therapists could be trained to conduct the treatment with excellent adherence.[18] To minimize disruption to ongoing group treatment, Team 1 and Team 2 therapists provided coverage for each other when needed. Three back-up therapists were trained for additional potential coverage should a therapist become ill, go on vacation or leave the study site.

All therapists were female to eliminate potential patient-therapist gender matching as a confounding variable.[27,28] Therapists were required to have at least two years of SUD treatment experience, a master's degree in an area that included training in psychopathology, and one year of group therapy experience. Therapists selected were randomly assigned to administer either GDC or WRG and to be part of either Team 1 or Team 2.

GDC and WRG therapists attended full day trainings conducted by Dennis Daley, PhD (the developer of GDC) and Shelly F. Greenfield, MD, MPH (the developer of WRG and PI of the study). To prevent "contamination" between the conditions, trainings were held on separate days, and therapists were instructed to discuss the trainings and the therapies only with their supervisors and therapists who were trained with them. During both trainings, therapists viewed videos of group sessions from the Stage I trial. Additionally, therapists received the treatment manuals and slides from didactic presentations.

Team 1 therapists began weekly conference calls with their supervisors in February 2009 and led groups from April 2009 to May 2010. To effect a smooth transition from Team 1 to Team 2, in January 2010 we implemented booster training for Team 2 therapists, where therapists reviewed tapes and slides, so they could begin leading groups in May 2010. During March 2010, they also listened to tapes of active groups and participated in weekly supervision calls. In April 2010, each Team 2 therapist joined her respective group as an observer for two groups, then conducted the group herself for the third session with the Team 1 therapist present, and finally assumed leadership of the group at the next session for the duration of the study.

We assessed the effectiveness of this transition at the end of the treatment phase of the study by asking therapists to answer the following question on a 5-point Likert scale (1 = not at all satisfied, 5 = extremely satisfied): “How satisfied were you with the transition from Team 1 to Team 2 therapists?”

Therapist Satisfaction and Retention—All therapists met weekly by conference call with their respective supervisors. Supervisors reviewed audio recordings of the previous week’s group(s) and rated therapist adherence to the treatment manuals. To further encourage adherence, therapists rated their own adherence and independent raters also rated a random sample of all tapes.

Slow enrollment can result in “lowered morale among idle or frustrated clinical staff.”[7](p309) Some therapists found it difficult to remain adherent to the manual when there were few group participants. In order to enhance therapist morale, on weekly supervision calls we strategized how to create a meaningful group experience with small numbers of participants.

Results

Recruitment

Following implementation of our strategies, each quarter of the two-year enrollment period resulted in increased recruitment and enrollment compared to the previous quarter, and the final quarter of the study had the largest number of participants recruited at each site (see Figure 3). These quarterly increases in recruitment and subsequent group enrollment resulted in the study achieving its target enrollment on time.

Maintaining Group Attendance

After implementation of group attendance strategies, there were no disruptions in the rolling group schedule, and the study was completed on time. The mean number of groups attended by all subjects was 7.92 *(SD* = 3.31). Figure 4 shows the average number of participants in the WRG and GDC groups as well as the percentages of groups with varying numbers of participants at both sites. Overall, the groups at McLean had significantly more participants (*M* = 3.12, *SD* = 1.08) compared to groups at SSTAR (*M* = 2.50, *SD* = 1.16), $t(446) = 5.893$, $p < .001$. While the overall recruitment at SSTAR was not significantly different than McLean, participants were generally more economically challenged with greater transportation difficulty, which may have contributed to the lower mean number of participants attending each group session.

Therapist Satisfaction with Training and Transition

There was no therapist attrition from either site. Six therapists rated their satisfaction with the Team 1 to Team 2 transition as 5, one rated it 4, and one rated it 3. The one therapist who offered comments about the transition stated that it was “pretty seamless.”

Discussion

Open-enrollment group therapy trials present specific challenges to participant recruitment, enrollment, and retention, as well as therapist retention and training. In this study, we implemented effective strategies for recruitment and retention to meet targeted sample size and maintain adequate group enrollment and continuous group treatment through the 24-month study. We also developed and implemented strategies to transition smoothly from one team of therapists to another, including providing effective initial and booster training. In addition, we provided ongoing supervision of therapists, which led to high therapist satisfaction and retention.

One limitation of our approach to addressing study challenges is that we implemented a number of strategies simultaneously. Therefore, we could not determine the relative contribution of any individual strategy to the improvement in participant recruitment. In addition, while we maintained continuous enrollment in six study groups (i.e., three at each site) over a 24-month period, a significant minority of groups fell below three participants in attendance. We also note that the average number of participants per group was lower at SSTAR than McLean. Variation in group attendance may be a factor in patient experience and could affect treatment outcomes. Such variation is a factor to be considered in any outcome analysis of open-enrollment group therapy.

In order to expand utilization of evidence-based SUD treatments in clinical settings, it is critical to conduct trials of effective treatments in a format that can be readily delivered in community practice. In the coming years, as healthcare reform makes population health ever more critical, group therapy will likely be a modality utilized to reach a wider range of the population. The process issues described in this paper are likely to have increasing relevance for forming and sustaining group therapy in both research and clinical settings. Our study demonstrated that effective strategies can be implemented to enhance participant recruitment and group retention, as well as therapist training, satisfaction, and retention in open-enrollment group therapy trials in real-world settings. As with other effectiveness studies, inclusion and exclusion criteria need to be chosen to maximize generalizability. To increase generalizability to clinic populations and practice in community-based programs, our study included participants who had dependence on a range of substances as well as other co-occurring psychiatric disorders, and the group treatments were implemented in an open-enrollment format.

Open-enrollment group therapy trials have specific challenges compared with studies of individual therapy or closed group therapy. They require continuous recruitment in order to adequately populate groups and keep them rolling. Additional staff may be required for continuous participant recruitment. Review of successful referral sources early in recruitment permits staff to focus their efforts on the highest yield sources. For studies with long enrollment periods where therapist attrition is a concern, training teams of therapists with a planned transition from one team to another can be an effective approach to maximize therapist retention and satisfaction.

Scientific Significance and Future Directions

Translation of research into practice requires effectiveness trials that are implemented in real-world settings. While group therapy implemented in an open format is a mainstay of substance abuse treatment in community settings, implementing effectiveness trials of open-enrollment substance abuse group therapy poses significant challenges. Strategies applied to group therapy clinical trials in community settings focused on enhancing participant recruitment and retention, as well as training and supervising therapists, can result in attaining target study sample size, adequate group size, and therapist satisfaction and retention. These strategies may be critical in providing evidence-based group therapy in both clinical and research settings.

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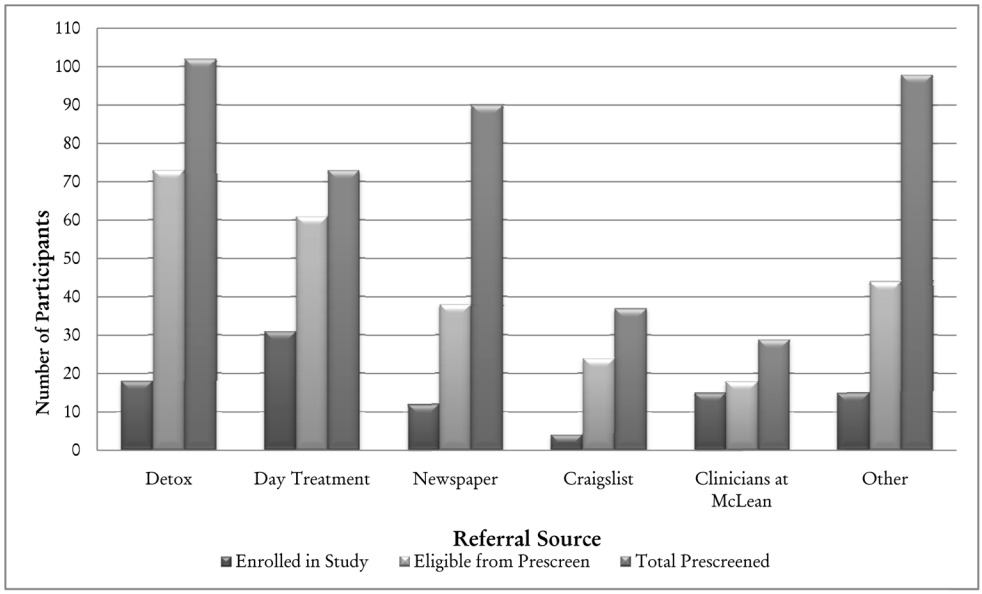
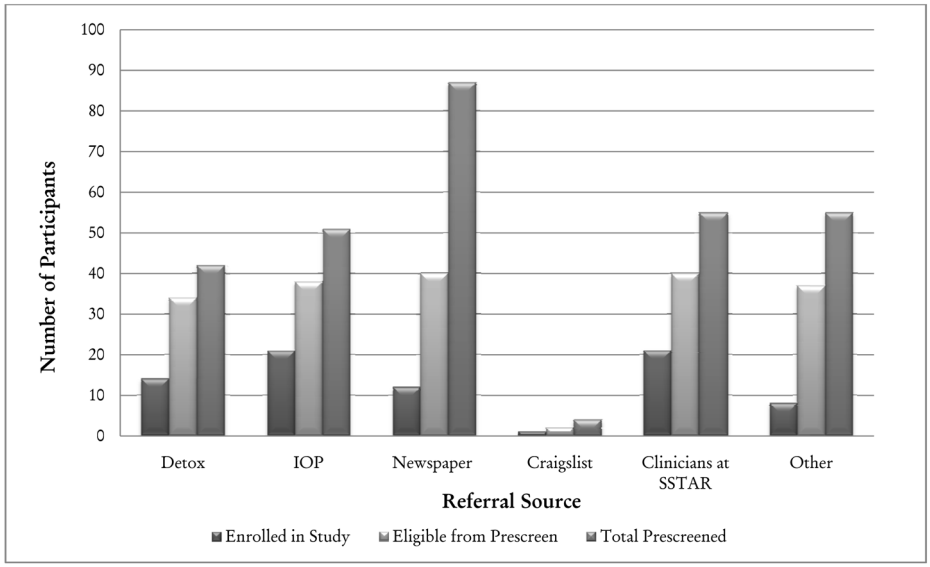


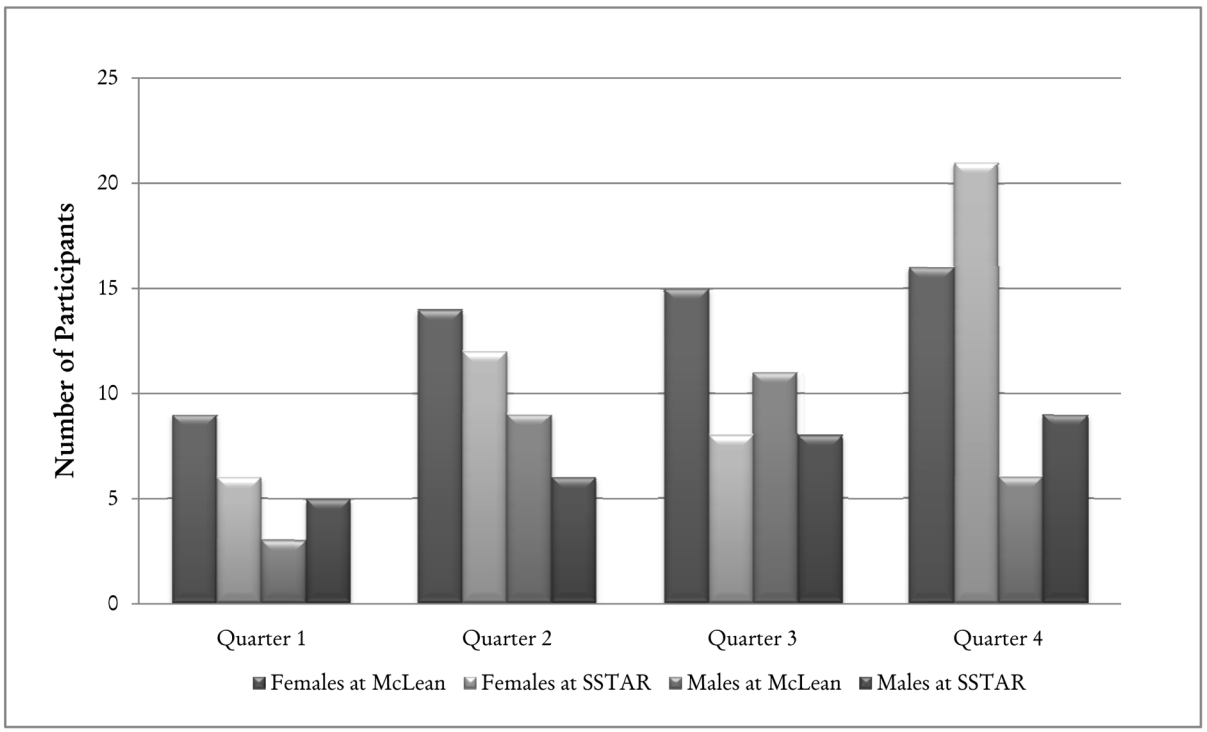
	Detox	Day Treatment	Newspaper	Craigslist	Clinicians at McLean	Other	Total
Enrolled in Study	18 (18.9%)	31 (32.3%)	12 (12.6%)	4 (4.2%)	15 (15.8%)	15 (15.8%)	**95**
Eligible from Prescreen	73 (28.3%)	61 (23.6%)	38 (14.7%)	24 (9.3%)	18 (7.0%)	44 (17.1%)	**258**
Total Prescreened	102 (23.8%)	73 (17.0%)	90 (21.0%)	37 (8.6%)	29 (6.8%)	98 (22.8%)	**429**

Figure 1.
Referral Sources at McLean



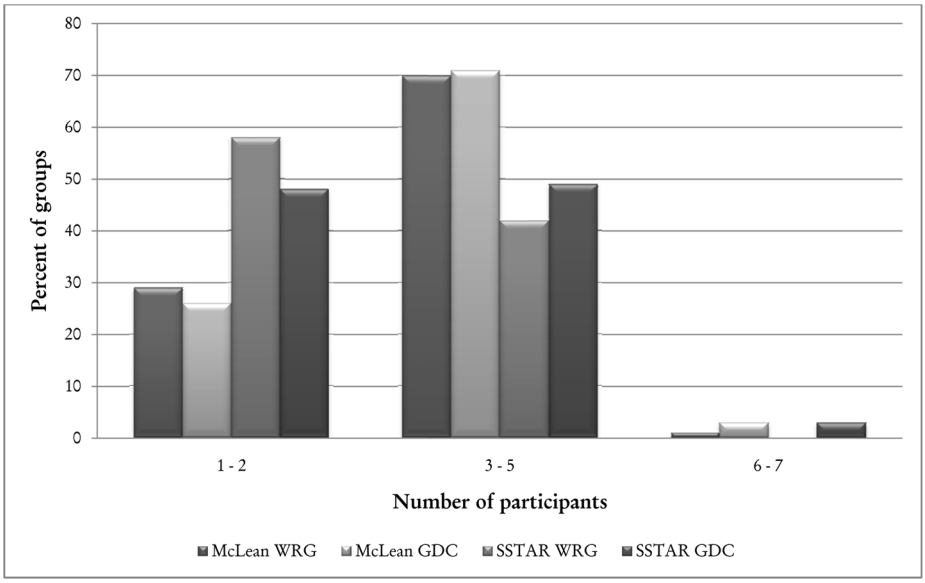
	Detox	IOP	Newspaper	Craigslist	Clinicians at SSTAR	Other	Total
Enrolled in Study	14 (18.2%)	21 (27.3%)	12 (15.6%)	1 (1.3%)	21 (27.3%)	8 (10.4%)	**77**
Eligible from Prescreen	34 (17.8%)	38 (19.9%)	40 (20.9%)	2 (1.0%)	40 (20.9%)	37 (19.4%)	**191**
Total Prescreened	42 (14.3%)	51 (17.3%)	87 (29.6%)	4 (1.4%)	55 (18.7%)	55 (18.7%)	**294**

Figure 2.
Referral Sources at SSTAR



	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Females at McLean	9	14	15	16
Females at SSTAR	6	12	8	21
Males at McLean	3	9	11	6
Males at SSTAR	5	6	8	9
Total	23	41	42	52

Figure 3.
Number of Participants Enrolled by Quarter



Percent of Groups at McLean and SSTAR with 1-7 Participants

	1 – 2 Participants	3 – 5 Participants	6 – 7 Participants
McLean WRG	29%	70%	1%
McLean GDC	26%	71%	3%
SSTAR WRG	58%	42%	0%
SSTAR GDC	48%	49%	3%

Figure 4.
Number of Participants in Group Sessions