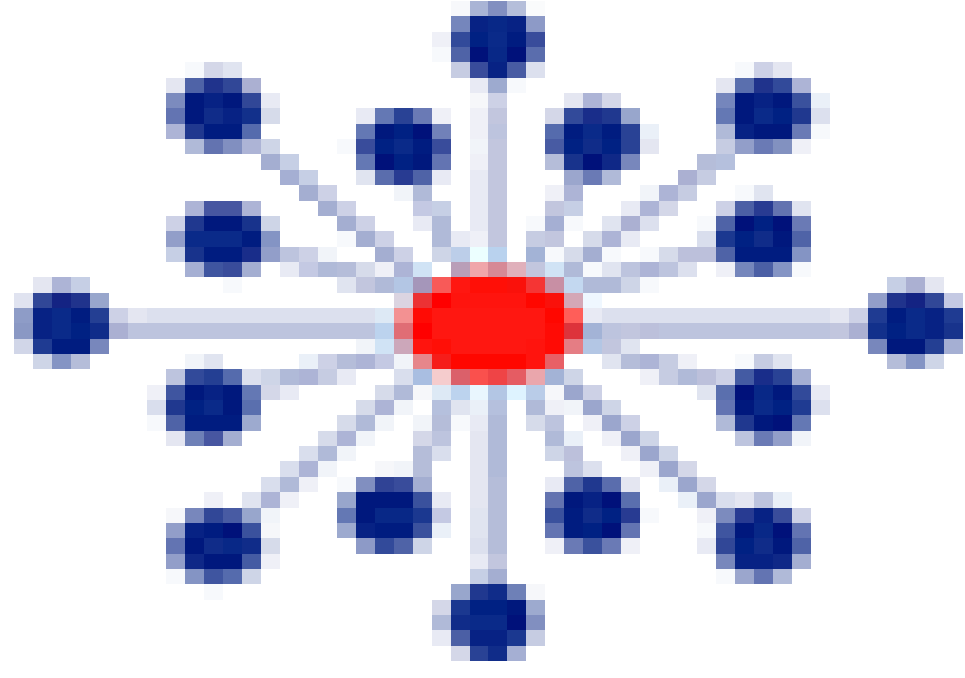




Using Respondent Driven Sampling (RDS) to Enhance Recruitment of Dually-Diagnosed Adolescent Clinical Trial Participants

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Introduction

- ◆ A lack of research on effective methods of recruiting dually-diagnosed adolescents to clinical trials has been a barrier to addressing research gaps in this important clinical population.
- ◆ We report on the use of respondent driven sampling (RDS)(Heckathorn, 1997) to enhance recruitment efforts at Lexington-Richland Alcohol and Drug Abuse Council (LRADAC).
- ◆ RDS is a method that is used for sampling “hidden” populations.
- ◆ RDS assumes that those best able to access members of “hidden” populations are their own peers.
- ◆ RDS was developed by Douglas D. Heckathorn in 1997 as part of a NIDA funded HIV prevention research project targeting drug injectors in several Connecticut cities.
- ◆ There is very limited literature to suggest that RDS has been used in other adolescent clinical trials.

Study Design and Methods

- ◆ A Randomized Controlled Trial of Osmotic-Release Methylphenidate (OROS-MPH) for Attention Deficit Hyperactivity Disorder (ADHD) in Adolescents with Substance Use Disorders (SUD) (CTN-0028)
- ◆ 16 week trial comparing the acute efficacy of OROS-MPH vs. placebo for ADHD in adolescents with ADHD and a SUD and the impact on substance treatment outcomes.
- ◆ All participants receive weekly individual manualized Cognitive Behavioral Therapy (CBT) targeting their SUD.
- ◆ Study participants are followed up at approximately one month.
- ◆ Each site has a target goal of 30 randomized participants.
- ◆ The study population includes adolescents between 13 to 18 years old with ADHD (DSM-IV) and at least one non-nicotine SUD (excluding methamphetamine abuse/dependence or past month use; and opioid dependence).
- ◆ LRADAC is one of 11 sites participating in the CTN multisite trial.
- ◆ LRADAC was initiated on March 16, 2006 as part of the 3 wave 1 sites.

Figure 1. Location of Community Treatment Programs participating in CTN-028

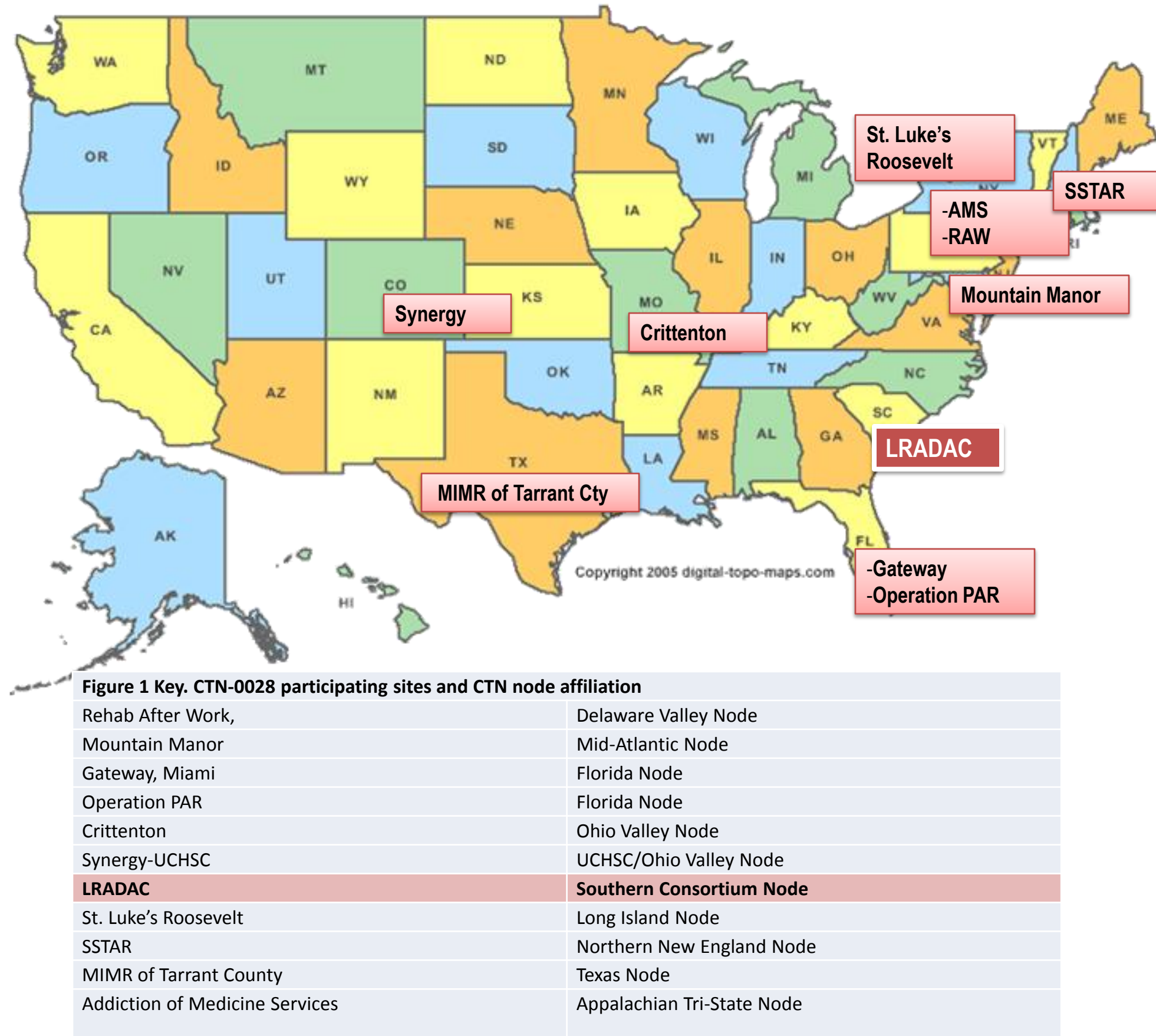


Table 1. Demographics

Characteristics	CTN-028-Overall Study N=303	LRADAC N=32
Sex		
Male	239 (78.9%)	28 (87.5%)
Female	64 (21.1%)	4 (12.5%)
Race		
Caucasian	184 (61.7%)	16 (50%)
African American	69 (23.2%)	16 (50%)
Native American	3 (1.0%)	0 (0%)
Asian	4 (1.3%)	0 (0%)
Pacific Islander	0 (0.0%)	0 (0%)
Other	18 (6.0%)	0 (0%)
Mixed Race	20 (6.7%)	0 (0%)
Chose not to answer	3 (1.0%)	0 (0%)
Ethnicity		
Hispanic	46 (15.2%)	1 (3.13%)

Respondent Driven Sampling

- ◆ Site recruitment efforts initially focused on evaluating adolescents meeting pre-screening criteria who were referred to the treatment program Lexington-Richland Alcohol and Drug Abuse Council (LRADAC) through existing referral sources (e.g. juvenile justice, social services, schools).
- ◆ Slower than expected recruitment prompted study staff to request IRB approval to compensate study participants who made a referral to the study (RDS)
- ◆ RDS was approved by the IRB and implemented as a recruitment method at LRADAC on April 6, 2007.
- ◆ A statement was added to the informed consent to explain the RDS procedures.
- ◆ The participant was given flyers to pass out to other people (e.g. peers, acquaintances) whom they thought would be eligible and interested in the study.
- ◆ The potential participant would have to contact the research office by telephone or in-person in order to be considered.
- ◆ If any flyers resulted in a successful completion of the informed consent process the referring participant would be compensated \$10.

Results

- ◆ RDS was approved and implemented as a recruitment method on April 6, 2007.
- ◆ Referrals were primarily received from the CTP existing referral sources (Table 2).
- ◆ Pre-RDS
 - ◆ 16 Randomized
 - 14 from existing CTP referral source
 - 2 from participant referrals
 - ◆ 1.14 average randomizations per month
- ◆ Post-RDS
 - ◆ 16 randomized
 - 5 from existing CTP referral source
 - 11 from RDS
 - ◆ 1.45 average randomizations per month
- ◆ LRADAC's overall treatment completion, follow-up and CBT compliance rates were very similar for participants randomized from existing CTP referral sources and participant referrals (RDS) (Figure 4).
- ◆ Each participant had an opportunity to complete 16 CBT sessions
- ◆ Participants were considered as study completers once week 16 visit was completed
- ◆ Follow-ups were completed 1 month following the 16 week visit

Table 2. Referral sources for overall study and LRADAC

Referral Source	CTN-028 Referrals	CTN-028 #Randomized (N=303)	LRADAC Referrals	LRADAC #Randomized (N=32)
Existing CTP Referral Sources (eg. Juvenile justice, social services, mental health clinics, etc.	811	198	62	20
New Referral Sources				
Community Outreach Personal Contacts				
Schools	140	27	26	0
Parent/Relative/Friend/Associate	111	33	*38	12
Primary Care/Medical Clinic	24	5		0
University Email	6	4	NA	NA
Media Advertising				
Bus Ad	33	5	2	0
Flyer/Brochure/Poster	68	3	1	0
Newspaper Ad	59	20	0	
TV Ad	10	3	NA	NA
Radio Ad	63	3	0	0
Online Ad	4	1	NA	NA
Unknown	4	1	NA	NA

*This total number represents participant referrals for LRADAC

Figure 2. Overall randomizations from referral sources

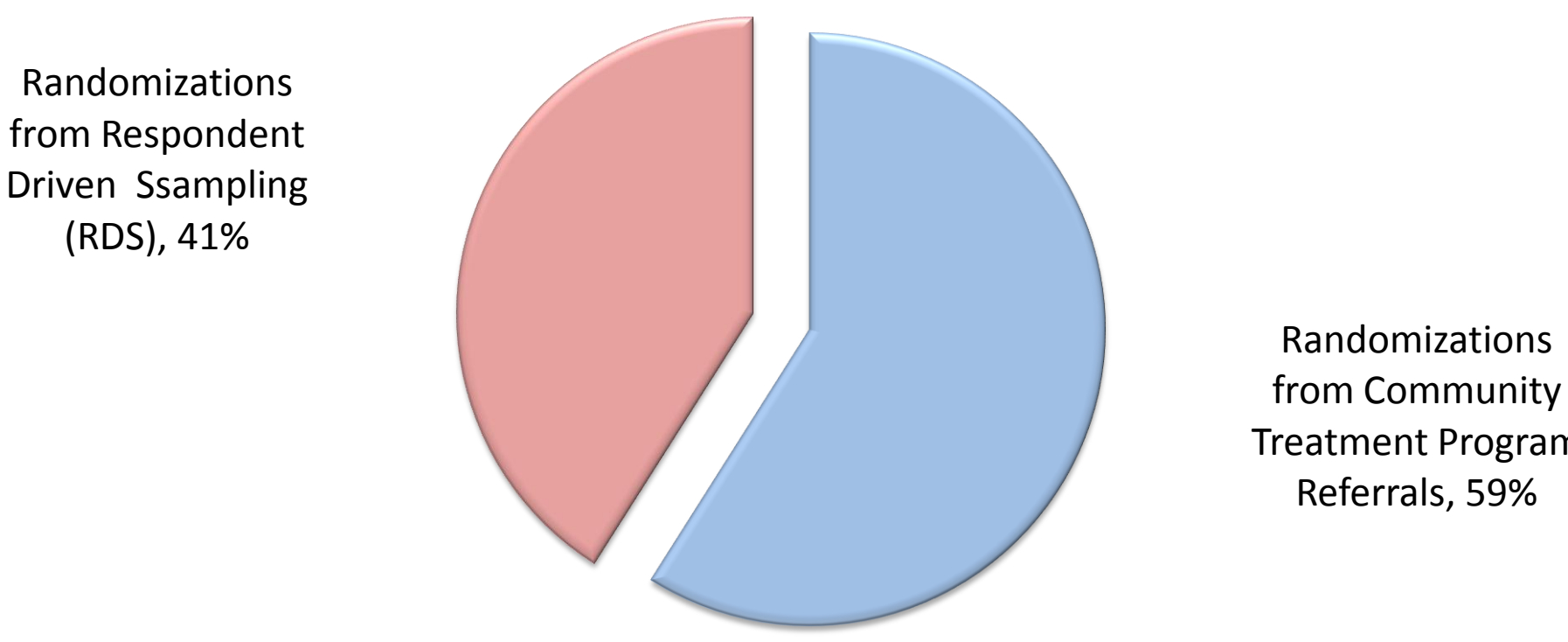


Figure 3. Proportion of randomizations from referral sources pre and post RDS

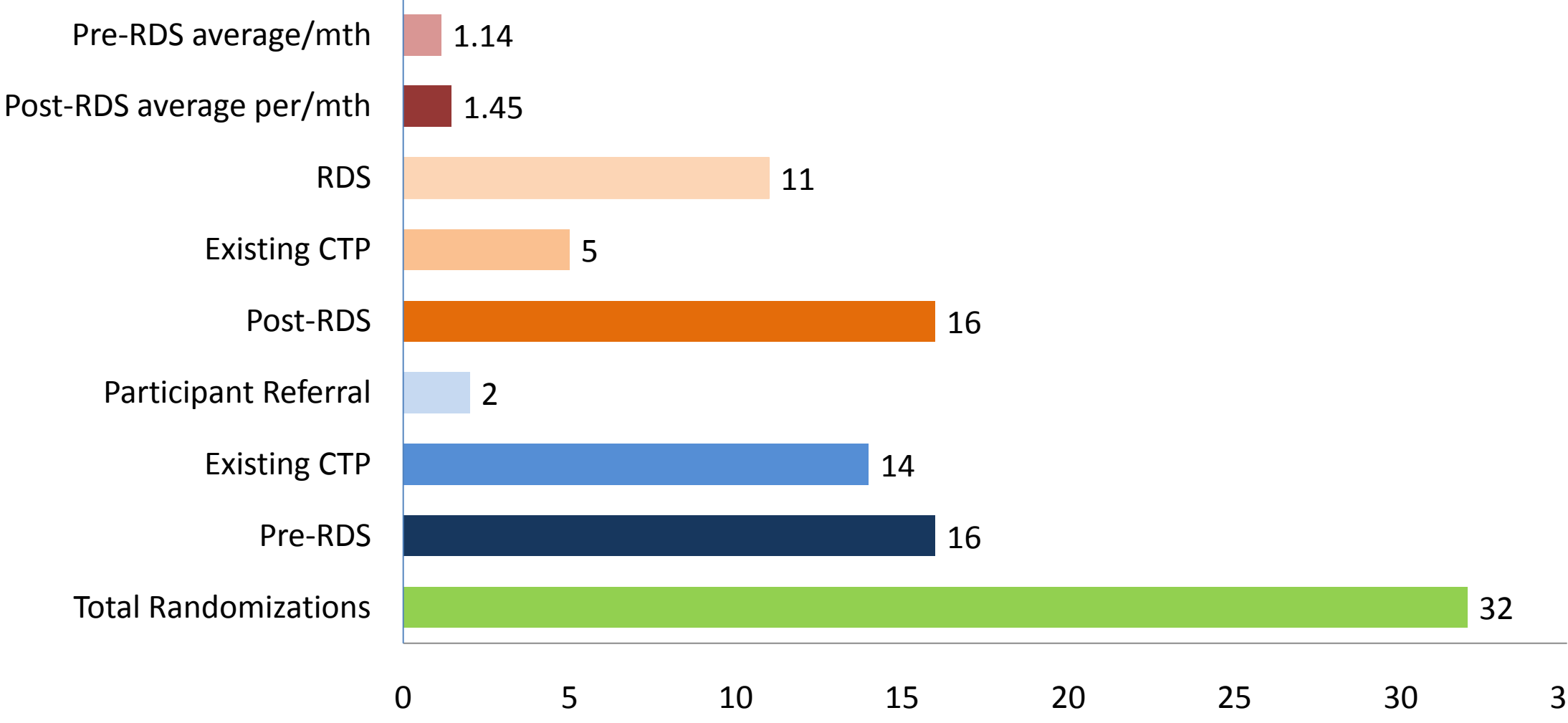
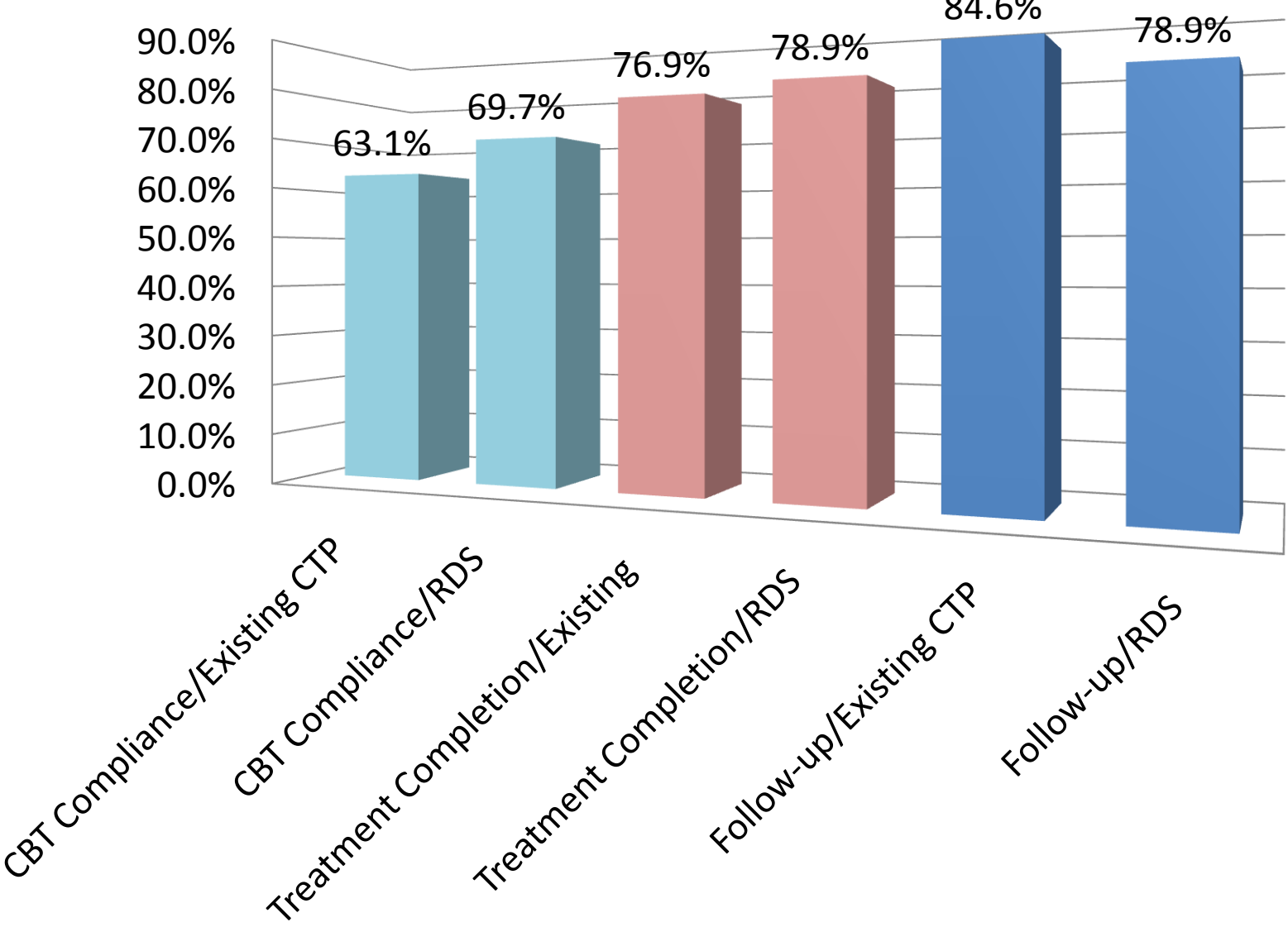


Figure 4. Compliance, retention and follow-up rates for LRADAC from referral sources



Conclusion

- ◆ RDS is an important and innovative recruitment strategy that enhanced recruitment efforts at LRADAC.
- ◆ Potential study participants who are referred by current study participants are just as likely to be compliant and retained in treatment as those who are referred from existing CTP referral sources.
- ◆ RDS may be an effective method in sampling the hard to reach adolescent or “hidden” population for clinical trials participation.
- ◆ Those best able to access members of the “hidden” population are their own peers.
- ◆ In future studies RDS should be considered, with IRB approval, as a viable recruitment strategy.

Limitations

- ◆ Limited sample size: data from one community treatment program
- ◆ Generalizability: data from this one community treatment program may not generalize to other treatment programs
- ◆ Differences between referral sources and randomizations by referral source across all sites may reflect differential staff effort and site specific recruitment strategy/targets

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- ◆ Lead Investigator: Paula Riggs, MD, University of Colorado at Denver and Health Sciences Center
- ◆ Co-Lead Investigator: Theresa Winhusen PhD, University of Cincinnati, Ohio Valley Node

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