Published in final edited form as:

Int J Eat Disord. 2012 September ; 45(6): 812–815. doi:10.1002/eat.22010.

Recruitment and Retention in an Adolescent Anorexia Nervosa Treatment Trial

Lisa Brownstone, A.B.¹, Kristen Anderson, A.M.¹, Judy Beenhakker, M.S.², James Lock, M.D., Ph.D.², and Daniel Le Grange, PhD.^{1,*}

¹Department of Psychiatry & Behavioral Neuroscience, The University of Chicago, Chicago, Illinois

²Department of Psychiatry & Behavioral Sciences, Stanford University, Stanford, California

Abstract

Objective—To investigate recruitment and retention for a randomized controlled trial (RCT) of adolescent anorexia nervosa (AN), as prior studies suggest that these are significant hurdles to completing meaningful RCTs in this population.

Methods—Retrospective analyses of recruitment and retention rates were conducted for a multi-site randomized controlled trial (RCT) of family-based treatment (FBT) vs. adolescent-focused therapy (AFT) recruiting adolescents between 12 and 18 years of age with AN.

Results—Adolescent participants were recruited from a variety of both medical and non-medical sources. Recruitment goals were met in time (October 2004 – March 2007). Percent retention rates were high across both treatment types (84% for FBT and 92% for AFT), and these rates did not differ significantly.

Discussion—These results reveal that recruitment and retention of adolescent patients with AN to RCT's are feasible in contrast to the experience in adult studies. It is likely that characteristics of our clinical programs make recruitment easier than in other settings, e.g., child and adolescent focused, specialized eating disorders program with an emphasis on outpatient treatment, recognized leaders in the field, and a history of clinical excellence with this population.

Keywords

recruitment; randomized controlled trial; anorexia nervosa; adolescent; retention

To date, few studies have looked at recruitment method in randomized controlled trials (RCTs) for eating disorders, particularly for anorexia nervosa (AN). Halmi and colleagues¹ sign a note of caution about treatment trials for adults with AN, specifically by showing the lack of information that has been gathered about how to recruit and retain participants in RCTs. These authors argue that RCTs for AN should not be initiated until more is known about how to recruit and retain this population. Participant recruitment in RCTs is an important yet often overlooked component of study design, perhaps in part due to the low base rate for AN and few published RCTs for this population. Successful recruitment procedures are often based upon anecdotal evidence from previous studies involving similar populations.² These methods for designing recruitment procedures are not always effective when applied to studies with differing designs and differing populations.

*Address correspondence to Daniel Le Grange, Department of Psychiatry & Behavioral Neuroscience, The University of Chicago, 5841 South Maryland Avenue, MC 3077, Chicago, IL 60637. Phone: 773-702-9927, Fax: 773-702-9929, legrange@uchicago.edu.

Gowers and colleagues³ published an early report on the complexities associated with recruiting participants for a RCT comparing inpatient and outpatient treatments for AN despite a busy inpatient service. These authors encountered a range of both practical and ethical challenges in accomplishing their recruitment goals. In addition, McDermott and her colleagues⁴ analyzed recruitment rates for three separate RCTs: a study recruiting women partially recovered from AN and two studies recruiting women with current bulimia nervosa (BN). This report finds that recruitment of women partially recovered from AN is a difficult task that requires widespread and intensive recruitment efforts over multiple sites and over a lengthy time-course. By contrast, recruitment of adult women with BN seemed a more achievable goal. In Halmi and colleagues' ¹ multi-site RCT of adult women with AN, recruitment as well as retention of participants were such significant struggle that the authors decided that they should not analyze their data.

Data about participant recruitment in adolescent eating disorders, while limited in scope and scale, are somewhat more promising. Recruitment rates appeared to be reasonable in recently published RCTs.⁵⁻⁷ Retention rates in these adolescent treatment studies were satisfactory with dropout ranging between 10-25%. One of these studies⁸ detailed their recruitment efforts for adolescents with BN to a treatment trial, which is in accordance with findings that adult BN patients can be recruited consistently and successfully to treatment trials.⁴

The current report is the second paper in the literature to analyze recruitment rates in an eating disorder treatment trial for adolescents. It draws from our earlier work⁸ and aims to investigate the feasibility of recruiting and retaining adolescents with AN for an RCT that was conducted at The University of Chicago and Stanford University from April 2005 to March 2009.

Method

The purpose of the two-site study was to compare different psychosocial treatments for adolescents with AN: family-based treatment (FBT) and adolescent focused therapy (AFT). Participants were randomized to one of these two treatment types and comparative results from the RCT are published elsewhere.⁹

Participants

Eligible participants in the RCT were males and females between the ages of 12 and 18 years of age who met Diagnostic and Statistical Manual of Mental Disorders 4th Edition (DSM-IV)¹⁰ criteria for AN without the amenorrhea criterion. In order to be eligible, patients also had to be living with at least one parent or guardian. Participants were excluded if their weight was outside a range of 75-85% Ideal Body Weight (IBW), age below 12 years or above 18 years, presented with a past or present psychosis, current acute suicidality, current medical instability, unwillingness to discontinue current treatment, and lack of parent/guardian involvement in treatment. Weight thresholds (IBW >85%) for study entry were calculated using the Centers for Disease Control and Prevention weight charts.¹¹ The research was reviewed and approved by The University of Chicago and the Stanford University institutional review boards.

Procedure

Interested individuals completed a phone triage and were scheduled for a baseline assessment to determine eligibility. The baseline assessment included both interview-based assessments and computer questionnaires. Eligible and willing participants were randomized to one of two manualized treatments for AN: FBT or AFT. According to treatment manual

protocol, those assigned to FBT were provided twenty-four 60-minute sessions of outpatient treatment, while those assigned to AFT were provided thirty-two 45-minute sessions of outpatient treatment, 8 of which were reserved for parent collateral sessions. Participants completed other assessments during treatment, and at end of treatment, 6-month follow up, and 1-year follow up.

Each site used similar strategies to recruit participants from October 2004 through March 2007, including distributing news releases, newspaper and radio advertisements, maintaining an updated website with study information, posting flyers, informing the local health care community, and contacting school professionals like counselors, teachers, school nurses, and athletic coaches. The Stanford University site was also able to draw participants from the onsite inpatient treatment program located in the Lucile Packard Children's Hospital. The majority of preliminary contacts interested in the study were by phone, while some preliminary contacts were made by e-mail. Some other contacts were made through the hospital when individuals called the hospital intake department interested in eating disorder treatment options.

Results

A total of 121 individuals (61 at The University of Chicago and 60 at Stanford University) participated in the AN treatment study. The average age of randomized participants was 14.4 (1.6) years. The majority of participants were female ($n=110$). Participants' average percent ideal body weight at baseline was 82% and body mass index was (BMI) was 16.1 (1.1). A sizeable portion of participants self-reported as ethnic or racial minorities (24%).

Recruitment

In total, 331 potential participants completed a full telephone screen. Of these, 175 individuals completed a baseline interview to determine eligibility, while 121 individuals were randomized into the study. Thus, 210 individuals were excluded following either phone or in-person interview and were not randomized into the study.

The most common reason for exclusion was weight being outside of the eligible range (80/210, 38%). Other common reasons for exclusion included dissatisfaction with treatments offered through the study (56/210, 27%), long commute (24/210, 11%), unwillingness to be randomized to a treatment type (9/210, 4%), age out of eligibility range (9/210, 4%), medical or psychiatric exclusion (7/210, 3%), and reason unknown (25/210, 12%).

Study participants were recruited from a wide range of sources, both medical and non-medical. Recruitment source was identified in 112 out of the total 121 participants (93%). Among those 112 participants, several reported more than one recruitment source, e.g. both physician and newspaper referral; therefore, there were 119 total responses recorded by the 112 participants for whom the recruitment source is known. The majority of participants reported referrals from outpatient medical providers, including physicians, therapists, social workers, clinic intake, and other outpatient treatment programs (44/119, 37%). Second to outpatient medical sources, inpatient medical programs referred a substantial number of participants (32/119, 27%). Medical referrals accounted for 64% of all referrals to the study. A substantial percentage of participants were referred to or learned about the study by means of non-medical sources, including school counselors, sports coaches, internet, advertisements, word of mouth, and self-education (43/119, 36%). The most frequent non-medical recruitment source was literature available to the public written by study principal investigators (14/119, 12%).

Recruitment source can also be categorized into self-initiated versus practitioner-referred. Self-initiated sources involved seeking information through self-education (books, newspaper articles, and internet), advertisement follow-up, and word of mouth. Practitioner-referred sources included physician, school-counselor, and therapist referrals. The majority of recruitment sources can be categorized as practitioner-referred (79/119, 66%). See Table 1 for frequencies of each referral source broken down into discrete categories.

In order to complete the study in the five-year period, the recruitment goal was to complete all 120 randomizations within 2.5 years, which equates to a rate of 3 participants randomized per month across the two sites, i.e. 1.5 randomizations at each site per month. Both sites together randomized participants at this rate, and were able to complete randomization and recruitment within the 2.5 years. See Figure 1 for an illustration of the number of randomizations across time as it relates to the necessary (projected) rate.

Retention

Study retention rates during treatment were high. Dropout status was defined as attendance of less than 6 treatment sessions in FBT and 8 treatment sessions in AFT; these numbers are equivalent in terms of treatment time. Of those assigned to FBT, there were 8 dropouts (14%) and 3 drop-outs (6%) for AFT. This difference in number of dropouts was not statistically significant. A small number of randomized participants did not receive any of the intervention (7% for FBT and 2% for AFT). It is difficult to ascertain the reasons for these individuals not returning for treatment following assessment. Speculating, some parents and/or adolescents decided to seek treatment elsewhere, avoidance of treatment in general, or realizing post-randomization that the assigned treatment was not the best option for their family. The majority of study participants attended a large percentage of the treatment dosage and few dropped out of the study. The average percentage of treatment dosage completed was 88% (84% for FBT and 92% for AFT). The difference in percentage of treatment dosage completed across the groups was not significant.

Additionally, follow-up assessment retention was high for both treatment types. Post-treatment assessment was gathered for the majority of study participants (84% for FBT and 87% for AFT). This difference in post-treatment assessment gathering across groups was not significant. Assessments were also collected for the majority of participants at 6-month follow-up (71% for FBT and 77% for AFT) and 12-month follow-up (72% for FBT and 82% for AFT), neither of these groups differences at 6- and 12-month follow-up were significantly different across groups.

Discussion

Consistent with previous findings, results reveal that it is possible to recruit and retain for adolescent AN treatment trials. The total number of participants was recruited within the 2.5-year recruitment period of the study at an average of three newly randomized cases per month across the two sites. Three major subcategories of sources were useful in recruiting study participants: inpatient providers, outpatient medical providers, and non-medical resources. Efforts to recruit this same population and similar populations likely must include communication through all three of these means.

Given that the majority of participants learned about the present study by means of medical and practitioner referrals, it seems that the most important recruitment source for the present adolescent AN RCT's was the medical and practitioner community. This could be explained because it is possible that adolescents already identified as suffering from AN by medical providers are more likely to be recruited to outpatient non-medication treatment studies. Whether this outcome is unique to an adolescent population is difficult to know. The large

role that medical providers played in serving as referrals to this treatment study may more broadly speak to the necessary role that the medical community must play in motivating individuals suffering from AN to seek treatment.

The current study was not only able to recruit adolescents to the trial in the required amount of time, but also was able to retain participants throughout treatment and post-treatment follow up assessments at promising rates. Retention rates for this adolescent AN RCT are quite different than those previously found in adult AN RCTs, e.g., between 37% and 51% treatment completion in Halmi et al., 2005¹. This may suggest that adolescents with AN are a more practical group to study in outpatient RCTs (at least in terms of recruitment and retention) than adults.

As an important note, there are characteristics of both University of Chicago and Stanford University's programs that likely make recruitment easier than in other settings, e.g., child and adolescent focused, specialized eating disorders programs with an emphasis on outpatient treatment, recognized leaders in the field, and a history of clinical excellence with this population. That being said, this current report paints a relatively positive picture of the potential for success in future adolescent eating disorder treatment RCTs.

Acknowledgments

Financial Disclosure

Dr. Le Grange is supported by the NIH (MH070620). Dr. Lock is supported by the NIH (MH070621). Drs. Le Grange and Lock receive honoraria from the Training Institute for Child and Adolescent Eating Disorders, LLC, as well as royalties from Guilford Press. Dr. Lock also receives royalties from Oxford University Press.

References

1. Halmi K, Agras W, Crow S, Mitchell J, Wilson T, Bryson S, Kraemer H. Predictors of treatment acceptance and completion in anorexia nervosa: Implications for future study designs. *Archives of General Psychiatry*. 2005; 62:776–781. [PubMed: 15997019]
2. Agras W, Marshall G, Kraemer H. Planning recruitment. *Circulation*. 1982; 66(IV):54–76.
3. Gowers S, Norton K, Yeldham D, Bowyer C, Levett G, Heavey A, Bhat A, Crisp A. The St George's prospective treatment study of anorexia nervosa: a discussion of methodological problems. *International Journal of Eating Disorders*. 1989; 8(4):445–454.
4. McDermott C, Agras W, Crow S, Halmi K, Mitchell J, Bryson S. Participant recruitment for an anorexia nervosa treatment study. *International Journal of Eating Disorders*. 2004; 35:33–41. [PubMed: 14705155]
5. Le Grange D, Crosby RD, Rathouz PJ, Leventhal BL. A randomized controlled comparison of family-based treatment and supportive psychotherapy for adolescent bulimia nervosa. *Archives of General Psychiatry*. 2007; 64:1049–1056. [PubMed: 17768270]
6. Lock J, Agras WS, Bryson S, Kraemer H. A comparison of short- and long-term family therapy for adolescent anorexia nervosa. *Journal of American Academy of Child and Adolescent Psychiatry*. 2005; 44:632–639.
7. Gowers S, Clark A, Roberts C, Griffiths A, Edwards V, Bryan C, Smethurst N, Byford S, Barrett B. Clinical effectiveness of treatments for anorexia nervosa in adolescents. *British Journal of Psychiatry*. 2007; 191:427–435. [PubMed: 17978323]
8. Hewell K, Hoste R, Le Grange D. Recruitment for an adolescent bulimia nervosa treatment study. *Int J Eat Dis*. 2006; 39(7):594–597.
9. Lock J, Le Grange D, Agras W, Moye A, Bryson S, Jo B. Randomized clinical trial comparing family-based treatment with adolescent-focused individual therapy for adolescents with anorexia nervosa. *Arch Gen Psychiatry*. 2010; 67(10):1025–1032. [PubMed: 20921118]
10. American Psychiatric Association. *Diagnostic and Statistical Manual for Mental Disorders*. 4th Ed.. APA; 1994. DSM-IV

11. Centers for Disease Control and Prevention. CDC Growth Charts for the United States: Development and Methods. Centers for Disease Control and Prevention; Atlanta, GA: 2002.

Figure 1. Randomizations across time as compared to projected number of randomizations required each month.

Table 1
Recruitment Source Frequency

Recruitment Source	Frequency	Percent
Inpatient	32	26.9
Clinic Intake	19	16.0
Physician	17	14.3
Literature available to public	14	11.8
Internet	13	10.9
Word of mouth	8	6.7
Other Outpatient Treatment Program	6	5.0
Newspaper, Radio, TV Advertisement	5	4.2
School contact	3	2.5
Therapist, Social Worker, or Case Manager	2	1.7
Total	119	100

Note: Total frequency does not add up to total number of participants (121), because some participants reported multiple recruitment sources and the recruitment source was unknown for 9 participants. The total (N=119) corresponds to the number of recruitment source responses from the 112 patients for whom recruitment sources were known.