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Implementation and outcomes of home-based treatments for adolescents with anorexia nervosa: Study protocol for a pilot effectiveness-implementation trial

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Abstract

Objective: Although family-based treatment (FBT) is considered a first line treatment for adolescent anorexia nervosa (AN), it is underutilized in community settings and is unavailable to many families for a multitude of practical reasons (e.g., costs of treatment, transportation constraints). Adapting FBT interventions for delivery in home- and community-based settings may reduce pragmatic barriers to treatment uptake and engagement.

Method: This pilot effectiveness-implementation trial will assess outcomes, implementation, and mechanisms of FBT adapted for the home setting (FBT-HB), delivered in the context of community-based behavioral health agencies. Adolescents with AN-spectrum disorders (n=50) and their caregivers will be randomly assigned to either FBT-HB or home-based treatment as usual (TAU; integrated family therapy approach). Caregivers and adolescents will provide data on weight, eating, and putative treatment mechanisms, including caregiver self-efficacy and adolescent eating- and weight-related distress. Implementation measures of feasibility, acceptability, and appropriateness will be measured among providers and participating families.

Hypotheses: We expect that FBT-HB will be feasible, acceptable, and appropriate, and will outperform TAU in terms of improvements in adolescent weight and eating-related

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psychopathology. We further expect that caregiver self-efficacy and adolescent eating- and weight-related distress, but not general distress, will show greater improvements in FBT-HB relative to TAU and will be associated with better adolescent weight and eating outcomes in FBT-HB.

Potential implications: The proposed study has clear potential to advance scientific and clinical understanding of the real-world effectiveness of FBT for AN, including whether adapting it for the home setting improves its accessibility and effects on treatment outcome.

Keywords

Anorexia nervosa; restrictive eating; adolescent; eating disorder; family-based treatment; adaptation; implementation; effectiveness; mechanisms; home-based treatment

Anorexia nervosa (AN) incurs high personal and societal burden (van Hoeken & Hoek, 2020), yet few patients ever receive treatment (Forrest, Smith, & Swanson, 2017) due to patient-/family-level and structural barriers (Kazdin, Fitzsimmons-Craft, & Wilfley, 2017). Family-based treatment (FBT) is a well-established outpatient intervention focused on normalizing adolescents' weight status and eating behaviors (Gorrell, Loeb, & Le Grange, 2019) via promoting caregiver efficacy for refeeding, and extinguishing adolescents' fear response to eating/weight gain, among other putative mechanisms (Lock & Nicholls, 2019). Despite its efficacy, FBT implementation is low outside of specialized research and private practice settings (Mussell et al., 2000), and its effectiveness in "real world" settings is understudied (Couturier & Kimber, 2015). Factors that may inhibit engagement include cost, transportation-related barriers, stigma, and family commitments impeding attendance (e.g., lack of alternative caregivers for other dependent children; Innes, Clough, & Casey, 2017). Telehealth offsets many of these concerns (Anderson, Byrne, Crosby, & Le Grange, 2017), however, many families and clinicians may prefer face-to-face treatment to enhance rapport-building, engagement, and management of safety concerns (Matheson, Bohon, & Lock, 2020).

Offering treatment in the home is another practical alternative to outpatient treatment that minimizes or eliminates transportation, discomfort in medical settings, and need for families to identify alternative caregivers (Lay, Blanz, & Schmidt, 2001). Home-based services typically represent an intermediate level of care for patients whose symptoms are too severe for outpatient therapy (e.g., Darwish, Salmon, Ahuja, & Steed, 2006; Lamb, 2009), yet who do not require or cannot access hospital-based care (e.g., due to geographic or financial constraints, lengthy waitlists). Despite its benefits, home-based treatment is resource intensive, costly, and may be undesirable to some families, making it potentially less scalable. Therefore, it may be most appropriate for adolescents at high risk for hospitalization to bridge an eventual transition to traditional weekly outpatient treatment.

Home-based treatment is supported by empirical findings derived from learning theories. Translational studies on addiction, anxiety disorders, and other behavioral health conditions suggest that new learning may be context-specific (Bouton & Todd, 2014), meaning that the setting (and other contextual factors) in which new learning occurs may become a cue promoting retrieval/repetition of new skills. Therefore, providing treatment in patients' naturalistic, day-to-day environments may enhance generalizability of newly learned

intervention skills, thereby enhancing long-term outcome (Podlesnik, Kelley, Jimenez-Gomez, & Bouton, 2017). Although context-dependent learning has not been studied in AN, this model may be especially salient for extinguishing habitual behaviors such as those characterizing AN (e.g., dietary restriction; Uniacke, Walsh, Foerde, & Steinglass, 2018), as habits may be particularly sensitive to context changes (Steinfeld & Bouton, 2020). Home-based adaptations of evidence-based treatments for other psychiatric disorders (e.g., obsessive-compulsive disorder) have demonstrated initial efficacy (Rowa et al., 2007), and two small studies of adolescents with eating disorders suggest that home-based treatment is feasible, acceptable, and efficacious (Flütsch et al., 2021; Herpertz-Dahlmann et al., 2021). FBT interventions might be especially amenable to application in a home-based model, as providers can participate in meals *in vivo* in settings in which they typically occur, observe and intervene around behaviors and familial interactions that might not be evident in traditional treatment settings, canvas the home to support appropriate food selection and meal preparation, and gather information about the home which might not otherwise be communicated (e.g., proximity of dining space to bathroom). Although FBT can be effective in outpatient settings even without inclusion of a family meal or presence of the ill adolescent (Le Grange et al., 2016a), some families (especially those with a more severely ill adolescent; E. K. Hughes, Sawyer, Accurso, Singh, & Le Grange, 2019) may want or need additional scaffolding, modeling, and support to implement FBT interventions effectively in the natural environment (Le Grange et al., 2021).

This pilot study evaluates FBT interventions adapted for a home-based model (FBT-HB) in the context of "real world" community-based behavioral health agencies, and assesses caregiver- and adolescent-level mechanisms of treatment outcome, as well as implementation outcomes, within a hybrid effectiveness-implementation design (Landes, McBain, & Curran, 2019). We hypothesize that FBT-HB will be acceptable, appropriate, and feasible and will out-perform home-based treatment as usual (TAU) with respect to adolescent weight and eating outcomes. We further expect that within-treatment improvements in caregiver self-efficacy, and reductions in adolescent eating- and weight-related distress (but not general distress), will be significantly greater in FBT-HB relative to TAU, and will be associated with better FBT-HB outcomes.

Methods

Design

Proctor's Implementation Outcomes Framework (Proctor et al., 2011), which proposes that implementation outcomes (e.g., acceptability, feasibility) are the effects of deliberate and purposive actions to implement new treatments, practices, and services, guides our design and data collection. Hybrid Type 1 designs focus on examining factors that influence implementation, but data collected through process evaluation—which can be concurrent or retrospective—do not inform the current effectiveness trial (Curran, et al., 2012).

Participants

Participants will include 50 adolescents (ages 12-18) with full-syndrome or subthreshold/atypical AN (e.g., all symptoms of AN are present but percentage median BMI is

in a “healthy” or overweight/obese range per CDC growth charts; Kuczmarski et al., 2000) and their caregiver(s), randomized to FBT-HB or TAU. Adolescents must be 1) eligible for home-based treatment in a community-based clinic; 2) living with at least one adult caregiver who is willing and able to engage in family treatment; 3) medically stable for outpatient treatment per physician assessment; 4) free of comorbid conditions contraindicating psychotherapy (e.g., psychosis) or affecting weight or appetite (e.g., diabetes); and 5) not pregnant or lactating. Families will be recruited in and around Providence, RI, and Pittsburgh, PA, through referrals from hospital-based and outpatient healthcare settings, and community advertisements. Interventionists (typically non-specialist bachelor’s- and master’s-level mental health workers with limited eating disorders expertise/training) will also be engaged in the research to complete implementation measures. All clinicians who agree to participate are eligible. Separate clinicians will administer FBT-HB and TAU to avoid cross-contamination of treatment arms.

This trial is registered at NCT05184556 and Open Science Framework (DOI: 10.17605/OSF.IO/42TEP), and received approval from the Lifespan IRB (#1672840).

Procedures

Families will be phone-screened to assess preliminary eligibility, then invited to complete consent/assent procedures and a baseline evaluation (see Figure 1). After eligibility confirmation, participants will be randomized via REDCap to FBT-HB or TAU in blocks stratified by AN status (full-syndrome vs. subthreshold/atypical) and clinical site. To achieve a representative sample, there are no a priori sample size targets for diagnostic groups. Eligible families (approximately 50% of whom are stepping down from higher levels of care, per current referral patterns at partnering agencies) will be assigned a clinician at the agency to which they were referred, or assigned an agency based on insurance coverage and current waiting lists. Clinicians will conduct a standard intake and offer an overview of treatment procedures. Follow-up assessments conducted by blinded research assistants will occur at 6-, 12-, and 24-weeks post-randomization. Blinding will be assessed after each family’s final visit. All adolescents undergo medical monitoring throughout treatment, regardless of treatment assignment. Clinicians who consent to participate will complete implementation measures every six months.

Interventions

All clinicians will undergo training prior to providing treatment. FBT-HB clinicians will review the FBT manual (Lock & Le Grange, 2013), then view a video-recorded 8-hour workshop conducted by a study author (DLG). TAU training is time-matched to FBT-HB training and focuses on classification, diagnosis, and outpatient mangement of AN. Clinicians in both conditions will receive weekly group-based supervision from a Ph.D.-level psychologist with expertise in AN. Clincians at all sites also receive more general weekly individual supervision from a Ph.D.- or master’s level psychologist as part of standard organizational procedures. Though dose and duration vary by clinical need and insurance coverage, home-based treatment typically is delivered in 1-2 hour sessions occurring at least twice per week. Weight and eating goals will vary by illness presentation, but we expect that most adolescents will need to gain weight to return to premorbid growth

trajectories and fully restore physical and psychological health (Seetharaman et al., 2017; Swenne, Parling, & Salonen Ros, 2017), even those who attained ≥95% of expected body weight according to CDC growth charts during hospital-based treatment.

FBT-HB: FBT-HB is an adaptation of manualized outpatient FBT, a triphasic treament focused on 1) uniting and empowering caregivers to take control of the adolescent's eating- and weight-related behaviors, including through a family meal; 2) transitioning control of eating back to the adolescent, as developmentally appropriate, once weight restoration is nearly complete and conflict around eating is reduced; and 3) processing general adolescent issues, negotiating a healthy parent-child relationship, and preventing relapse. Based on formative work with stakeholders from partnering agencies (i.e., team leaders/supervisors, clinicians, and families), we determined that FBT-HB involves the following modifications: 1) altered dose of treatment (30-40 hours of treatment over 12-32 weeks vs. 16-20 hours of treatment over 6-12 months); 2) multiple family meals; 3) clinician assistance preparing and supervising meals with the adolescent (e.g., at school), meal planning, and grocery shopping; 4) clinician attendance at medical appointments to ensure continuity of care and consistent messaging across providers; and 5) introduction of distress tolerance and emotion regulation skills (which are not contraindicative to FBT and could potentially help adolescents better tolerate FBT interventions; Accurso, Astrachan-Fletcher, O'Brien, McClanahan, & Le Grange, 2018) to supplement family sessions when caregivers are unavailable for multiple hours of therapy each week. Treatment phases generally follow the same chronology as standard FBT, but given the acuity of illness presentation and altered dose of treatment, Phase III is typically not covered in great detail.

TAU: TAU is a supportive family therapy approach including psychoeducation and elements of cognitive-behavioral therapy and dialectical behavioral therapy to enhance coping and practice of adaptive behaviors. Consistent with these approaches, proposed mechanisms include shape/weight concerns and general distress. To represent "real world" practice for AN (Gabel, Pinhas, Eisler, Katzman, & Heinmaa, 2014), families in TAU may be referred for additional nutritional counseling.

Measures

Demographics and concurrent medical, behavioral, or psychiatric treatment will be self- or caregiver-reported; concurrent medical problems will be collected from physicians at baseline, and regularly throughout treatment to assess medical stability (see Table 1). Comorbid psychopathology will be assessed via the Schedule for Affective Disorders and Schizophrenia for School-Aged Children (6-18)-Present and Lifetime Version (K-SADS-PL), a structured clinical interview assessing common psychiatric disorders in youth that has adequate psychometric properties (Kaufman et al., 1997; Kragh et al., 2019).

Implementation: The Abbreviated Acceptability Rating Profile (AARP; Tarnowski & Simonian, 1992) is a brief, reliable measure of treatment acceptability that will be administered to clinicians, caregivers, and adolescents. The Intervention Appropriateness Measure (IAM; Weiner et al., 2017) is a brief clinician-completed measure of appropriateness that has good reliability and validity (Weiner et al., 2017). Caregiver and

adolescent perceptions of appropriatness will be assessed via the Therapy Suitability and Patient Expectancy (TSPE; Le Grange et al., 2016b) scale, which has been widely used in eating disorders research (Accurso et al., 2018; Le Grange et al., 2016b; Lock et al., 2015). Feasibility will be conceptualized as the percentage of eligible families who engage in a baseline evaluation, and the percentage who enroll in the assigned treatment, as well as treatment attendance and completion rates. Clinicians will complete the Feasibility of Intervention Measure (FIM; Weiner et al., 2017) which has adequate psychometric properties. Fidelity will be measured via clinician self-report and caregiver report on the Multitheoretical List of Therapeutic Interventions-30 items (MULTI-30; Solomonov, McCarthy, Gorman, & Barber, 2019) and Therapeutic Technique Scale (TTS; Accurso et al., 2018). We will also record sessions, and a randomly selected 20% of recordings will be coded for fidelity according to a standardized measure (Forsberg et al., 2015). Sessions will be recorded in TAU to ensure independence of treatment conditions and minimize the possibility of unbalanced treatment effects attributable to expectancy biases. Families will participate in qualitative interviews at end-of-treatment to describe their experiences of treatment, barriers to engagement, and strategies for improvement in future trials.

Effectiveness: Adolescent height/weight will be measured to determine BMI. Eating disorder symptoms will be assessed via the Eating Disorder Examination (EDE; Fairburn & Cooper, 1993), which has excellent reliability and validity (Berg, Peterson, Frazier, & Crow, 2012). Primary adolescent outcomes will be change in BMI percentile, consistent with the recommended approach (Le Grange et al., 2012), and change in eating-related psychopathology.

Treatment mechanisms: Adolescent general distress will be measured via self-report on the Positive and Negative Affect Scale (PANAS; Watson, Clark, & Tellegen, 1988) which has good internal consistency and construct validity (Chorpita & Daleiden, 2002; A. A. Hughes & Kendall, 2009). Adolescent eating disorder-specific distress will be measured via self-report on the ED-15 (Tatham et al., 2015), Fear of Food Measure (FOFM; Levinson & Byrne, 2014), and Eating Disorder Fear Questionnaire (EFQ; Levinson, Vanzhula, & Christian, 2019); and via caregiver report on the Eating Disorder Symptom Impact Scale (EDSIS; Sepulveda, Whitney, Hankins, & Treasure, 2008). All four measures have good reliability and validity (Levinson & Byrne, 2014; Levinson et al., 2019; Sepulveda et al., 2008; Tatham et al., 2015). Caregivers will self-report their general- and eating disorder-related self-efficacy via the General Self-Efficacy Scale (GSES; Schwarzer & Jerusalem, 1995) and Parent vs. Anorexia Nervosa (PvAN) scale (Rhodes, Baillie, Brown, & Madden, 2005), respectively, both of which have good psychometric properties (Byrne, Accurso, Arnow, Lock, & Le Grange, 2015; Luszczynska, Scholz, & Schwarzer, 2005; Robinson, Strahan, Girz, Wilson, & Boachie, 2013). Adolescents and caregivers will complete a treatment skills checklist (TSC) incorporating both FBT-specific and non-specific treatment skills (to enhance relevance for TAU families and avoid biasing families in either condition to a particular treatment orientation) to assess how often skills were practiced across different locations/contexts (e.g., home, school).

Power analysis

Sample size was determined based on estimated recruitment rates over 3 years, and the minimal sample necessary to estimate population standard deviations in a pilot study for an assumed effect size between *d*=.2-.5 with 80% power. Sample sizes for pilot studies with 22 participants per treatment arm have been justified to find effects as low as *d*=.5 (Whitehead, Julious, Cooper, & Campbell, 2016).

Data analytic plan

Preliminary analyses will include descriptive statistics to examine distributional and psychometric properties of the variables. Variables will be transformed to achieve normality, if necessary. All estimates will be accompanied by 95% confidence intervals (CIs). We will examine attrition by comparing study completers to dropouts on sociodemographic and baseline characteristics. We will examine the success of the stratified randomization by examining between-group differences at baseline. Missing data will be handled with full information maximum likelihood or multiple imputation and all statistical assumptions will be checked. Given the randomization protocol, main analyses will not adjust for covariates; however, we will examine the potential influence of confounders [e.g., age, illness severity/duration, hours of treatment contact (i.e., dose), prior treatment exposure (including psychotropic medication usage), clinical site] with sensitivity analyses.

Analysis of implementation measures will be primarily descriptive. We will use Fisher's exact and *t*-tests to compare intervention conditions on implementation measures. Specifically, we will calculate the between-groups intervention effect size and 95% confidence intervals (CIs) for all outcomes to inform clinically meaningful differences from which to generate empirical power estimates for a confirmatory trial. Treatment effects on adolescent weight and eating will be assessed using multilevel modeling to investigate pre-post differences in BMI percentile and EDE trajectories by group across major time points. Finally, to investigate changes in caregiver self-efficacy and adolescent distress as putative FBT-HB mechanisms, we will first use growth curve modeling to estimate mean levels of caregiver self-efficacy and adolescent distress at the end of the study. To assess whether these improvements are associated with FBT-HB outcome, we will use rates of change in self-efficacy and distress, respectively, throughout the assessment period as predictors of end of study adolescent weight and eating outcomes using general/generalized linear mixed models.

Conclusion

Adapting FBT interventions for delivery in the home presents one promising and novel avenue for addressing barriers to treatment access that may impede optimal engagement and outcome in treatment for adolescent AN. Other approaches may include applying FBT through telehealth, or matching treatments to families' unique presentations and preferences. While delivering FBT interventions in the home is designed to minimize burden on the family system, it may present additional burden for clinicians in the form of increased time/travel, safety concerns, and challenges maintaining patient confidentiality. All of these factors can contribute to burnout, which can affect quality of care and promote turnover,

underscoring a need for additional support through peer supervision/consultation and other strategies (Johnson et al., 2018). Furthermore, given its intensity, home-based treatment is potentially less scalable (although delivery by non-specialist providers is a strength), and research is needed to understand characteristics of families for whom it is most appropriate (e.g., those at high risk for hospitalization/re-hospitalization and inability to access or pay for hospital-based treatment) as well as its cost-effectiveness (Boege, Corpus, Schepker, Kilian, & Fegert, 2015). Other considerations include a need to attend to aspects of clinician involvement that may inadvertently undermine caregiver efficacy (e.g., overly directive stance during meal preparation/supervision), and thoughtful discussions around clinicians' participation in family meals, as declining to eat with the family in the home may limit rapport-building and trust.

Next steps, should FBT-HB demonstrate effectiveness, will be to conduct a larger definitive trial comparing FBT-HB to standard outpatient FBT and to a home-based credible control, testing specific implementation strategies to increase uptake, identified through the current trial, to examine long-term outcomes and treatment moderators (including more rigorous slope- or profile-based analyses of differences between individuals with full-syndrome and subthreshold or atypical AN, who may have differing treatment goals). A subsequent trial would also facilitate more rigorous assessment of FBT-HB mechanisms (e.g., using ecological momentary assessment). Taken together, the proposed project has strong potential to inform future studies designed to expand the reach of evidence-based interventions for adolescent AN, and aligns closely with public health priorities to optimize outcomes of evidence-based treatments and test their effectiveness in community-based settings while also collecting important contextual information to inform implementation efforts.

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Data availability statement:

Formal data sharing proposal and agreement forms for the study can be requested from first author Andrea Goldschmidt (goldscha@pitt.edu).

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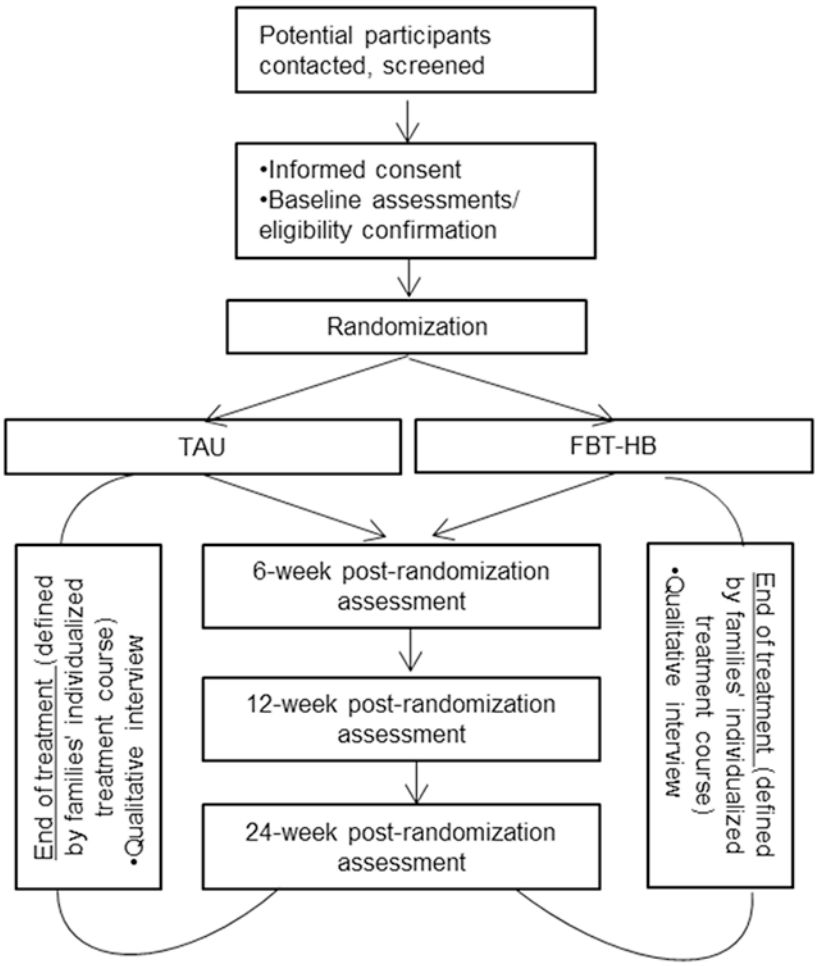

Figure 1.
Schedule of study procedures

Table 1.

Summary of measures

Construct	Measure	Respondent/Format	Time point				
Patient outcomes							
			Week 0	Week 6	Week 12	Week 24	Post-tx
Descriptives	Age, gender, race, ethnicity, SES	A, C_s	X				
	Concurrent treatment	C_a	X	X	X	X	
	Medical problems	C_a, Physician	X	X	X	X	
Primary outcomes	Adolescent height and weight	Measured	X	X	X	X	
	EDE	A (interview)	X	X	X	X	
Comorbid diagnoses	K-SADS-PL	A (interview)	X	X	X	X	
Family-level implementation outcomes							
			Week 0	Week 6	Week 12	Week 24	Post-tx
Acceptability	AARP	A, C_s	X	X	X	X	
Appropriateness	TSPE	A, C_s	X	X	X	X	
Experience of tx	Qualitative interview	A, C_s					X
Organization-level implementation outcomes							
			Pre-training		Post-training		F/U
Acceptability	AARP	Clinician	X		X		X
Appropriateness	IAM	Clinician	X		X		X
Feasibility	Rate of recruitment	Staff recorded	N/A		N/A		N/A
	Completion rate	Staff recorded	N/A		N/A		N/A
	IFM	Clinician	X		X		X
Fidelity	TTS	Clinician, C_c	Each session				
	MULTI-30	Clinician, C_c	End of treatment for each family				
	Session recordings	Staff coded	N/A		N/A		N/A
Treatment mechanisms							
			Week 0	Week 6	Week 12	Week 24	Post-tx
Distress	ED-15	A	X	X	X	X	

Construct	Measure	Respondent/Format	Time point			
	FOFM	A	X	X	X	X
	EFQ	A	X	X	X	X
	EDSIS	C_a	X	X	X	X
	PANAS	A	X	X	X	X
Self-efficacy	GSES	C_s	X	X	X	X
	PvAN	C_s	X	X	X	X
Adherence	TSC	A, C_s	X	X	X	X

Note: A=adolescent self-report; C_S=caregiver self-report; C_a=caregiver reporting on adolescent, C_C=caregiver reporting on clinician. Clinician follow-up (F/U) occurs every 6 months.

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