UNIVERSITY of SOUTH FLORIDA
Research & Innovation

PROTOCOL TITLE:

A Mobile Health Solution to Improve Between-Session Skills Practice in Youth Mental Health Treatment

PRINCIPAL INVESTIGATOR:

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VERSION NUMBER/DATE:

V11. July 27, 2023

REVISION HISTORY

***This table should only be used during submission of a Modification application to the IRB.**

Revision #	Version Date	Summary of Changes	Consent Change?
1	05/18/2021	Added the following: Attitudes Toward Homework Questionnaire for providers to complete at baseline and post-trial; missing question from the first page of the CATS-Y and CATS-P; weekly audio recording upload form; weekly email about providers uploading audio files. Made minor edits to the following: weekly emails about provider referrals; families phone screen; families and providers demographics; HRS-II questions for simplicity; embedded informational video in the redcap referral form and edited the end of the video to reflect this. Revised the following consent forms to improve clarity: K23 Aim 1 Caregivers Trial Consent and Permission, Version #2; K23 Aim 1 Providers Trial Consent, Version #2; K23 Aim 1 Youth Trial Assent, Version #2 Revised protocol to add the Attitudes Toward Homework Questionnaire.	Y
2	6/22/2021	Made minor edits to the following: HRS-II questions. Revised protocol to add ClinicalTrials.Gov NCT# and update abbreviations on screening questionnaires for consistency.	N
3	7/7/2021	Revised protocol to increase provider sample size to 30 and family sample size to 76	Y

		Revised the following consent forms to update sample sizes: K23 Aim 1 Caregivers Trial Consent and Permission, Version #3; K23 Aim 1 Providers Trial Consent, Version #3; K23 Aim 1 Youth Trial Assent, Version #3	
4	12/1/2021	Revised protocol to include the Assessment of Core CBT Skills (ACCS) to assess provider's CBT delivery. Added the following document: Assessment of Core CBT Skills (ACCS)	N
5	3/1/2022	Revised protocol to include option for families to be able to opt out of audio recording their therapy sessions. Made minor edits to the K23 Aim 1 Study Introduction Script about family's option to audio-record therapy sessions and K23 Aim 1 Provider Family Referral Form with updated video link. Revised the following consent forms with updates: K23 Aim 1 Caregivers Trial Consent and Permission; K23 Aim 1 Providers Trial Consent; K23 Aim 1 Youth Trial Assent.	Y
6	3/21/2022	Revised protocol to increase provider sample size to 40. Revised the following consent forms to update sample sizes: K23 Aim 1 Caregivers Trial Consent and Permission; K23 Aim 1 Providers Trial Consent.	Y
7	5/10/2022	Revised protocol to include the re-consent procedure if a study family changes therapists and the verbal re-consent if a youth turns 18-years old during the study. Revised the following consent forms: K23 Aim 1 Caregivers Trial Consent and Permission; K23 Aim 1 Youth Trial Assent; Added the following consent form: K23 Aim 1 Youth 18+ Trial Consent.	Y
8	7/7/2022	Revised protocol to increase provider sample size to 60 and update provider compensation to be sent after family enrollment. Currently enrolled providers will not be re-consented, but will be contacted via phone call and email to be updated with the changes in compensation. Revised the following consent forms to update sample sizes: K23 Aim 1 Caregivers Trial Consent and Permission; K23 Aim 1 Providers Trial Consent; K23 Aim 1 Youth 18+ Trial Consent. Uploaded the following script to provide current providers with updated compensation procedures: K23 Aim 1 Provider	Y

		Compensation Update Script	
9	9/1/2022	Revised protocol to clarify provider compensation. Revised the following consent form to clarify provider compensation: K23 Aim 1 Providers Trial Consent	Y
10	7/27/2023	Revised protocol to remove the requirement of having been in the CBT+Adhere.ly condition to participate in the post-trial interviews. Added that we will be conducting post-trial interviews with up to ≤20 providers, ≤10 of whom that referred families and ≤10 of whom did not refer families to the study. Uploaded revised versions of K23 Aim 1 Trial Post-Trial Interview – Providers and K23 Aim 1 Trial Post-Trial Interview – Families to update interview questions. Uploaded K23 Aim 2 Providers Impl Interview and K23 Aim 1 Post-Trial Interviews Verbal Consent. Uploaded revised version of Aim 2 Interview Recruitment Email and K23 Aim 2 Providers Impl Interviews Verbal Consent. Currently enrolled providers will not be re-consented, but we will contact 10 providers who were not in the CBT+Adhere.ly group via phone call to be updated with the changes and will obtain verbal consent to participate in post-trial interviews.	Y

Table of Contents

1.0 Study Summary

1.1

Study Title	A Mobile Health Solution to Improve Between-Session Skills Practice in Youth Mental Health Treatment
Study Design	Randomized trial methodology with assessments
Primary Objective/Purpose	The purpose of this study is to preliminarily evaluate Adhere.ly, a web-based platform to improve provider implementation and patient engagement in homework (i.e., between-session practice of skills learned during therapy) during child mental health treatment by conducting a small-scale feasibility trial in community practice settings comparing Cognitive Behavioral Therapy (CBT) to CBT+Adhere.ly.
Secondary Objective(s)/Purposes	To assess strategies for implementing Adhere.ly in community practice settings.
Research Intervention(s)	Cognitive Behavioral Therapy
ClinicalTrials.gov NCT #	NCT04931199
Study Population	Masters-level mental health providers; Treatment seeking children ages 7-17 years and their caregivers
Sample Size	N=242 n=60 providers; 76 youth patients; 76 caregivers; ≤10 community leaders; ≤10 supervisors; ≤10 senior leaders
Study Duration for individual subjects	Up to 12 months for providers 6 months for families
Study Specific Abbreviations/ Definitions	CBT=Cognitive Behavioral Therapy EBT=Evidence-Based Therapy IOM=Institute of Medicine

2.0 Objectives

2.1 The objectives of this project are to preliminarily evaluate Adhere.ly (https://adhere.ly/), a web-based platform to improve provider implementation and patient engagement in homework (i.e., between-session practice of skills learned during therapy) during child mental health treatment, conduct a small-scale feasibility trial in community practice settings comparing Cognitive Behavioral Therapy (CBT) to CBT+Adhere.ly, and begin to assess strategies for implementing Adhere.ly in community practice settings.

Aim 1. Conduct a feasibility trial comparing CBT to CBT+Adhere.ly
The trial will include 60 mental health providers randomized to deliver standard CBT (n=30) vs. CBT+Adhere.ly (n=30) and 76 treatment seeking youth (ages 7-17) with clinically elevated symptoms of anxiety, depression and/or PTSD and their caregivers, referred by providers; each provider will treat 3 study cases. Clinical outcomes (i.e., anxiety, depression, PTSD, disruptive behavior) will be assessed at baseline and 3- and 6-months post-baseline. Study targets (i.e., homework use and adherence) will be assessed via session audio recordings and weekly patient report. Post-trial qualitative interviews will be conducted with ≤20 providers and ≤10 families.

Aim 2. Assess strategies for implementation in preparation for a large-scale trial We will conduct remote, 30-minute individual qualitative interviews with ≤10 community-clinic providers, ≤10 supervisors, and ≤10 senior leaders.

2.2 This is a feasibility trial and is not powered for hypothesis testing.

3.0 Background

3.1 Mental health disorders affect 1 in 4 youth in the US and are associated with costly physical and behavioral health problems. The quality of community mental health services these patients receive vs. should receive is highly variable and characterized as a "quality chasm" by the IOM.[1] Homework is integral to high quality EBTs for many clinical conditions (e.g., MH, substance use, chronic pain, diabetes).[2–5] Homework exercises (e.g., self-monitoring, relaxation, exposure, parent behavior management) are assigned by providers in-session and completed by patients between sessions with the goal of "practicing" therapeutic skills. There are numerous benefits to homework use (i.e., assignment and review by providers) and adherence (i.e., quantity and quality of completion by patients).[6,7] Homework enables the generalization of skills and behaviors learned during therapy, provides continuity between sessions, allows providers to better grasp patients' learning, and strengthens that learning, leading to improved maintenance of treatment gains.[8,9] Meta-analytic and systematic reviews have shown that homework use and adherence predict and increased treatment engagement, decreased treatment dropout, and medium-to-large effects on improvements in clinical outcomes for use (d=.48-.77) and adherence to (d=.45-.54) homework.[2,8–13] Simply explained, 68% vs. 32% of patients can be expected to improve when therapy involves homework.[2]

Despite its many benefits, homework is significantly underutilized in mental health treatment. Providers for child and adult patients use homework in an average of 57% of sessions, and only 25% of providers report using systematic procedures for recommending homework.[14] A national survey revealed that 93% providers estimate

rates of patient adherence to homework to be low to moderate.[15] Only ~55% of family providers report using homework "often" to "almost always," and studies report low to moderate rates of youth/caregiver adherence (~39-63%).[16–23] There are many barriers to successful homework implementation. Providers experience difficulty with remembering to assign and assess homework, communicating rationale and instructions, providing adequate reinforcement, deciding what to assign, and assigning exercises flexibly and creatively. Patients experience difficulty remembering when, how, and why assignments should be completed and lack resources to do assignments effectively.[24]

Among adults aged 18-49 years (likely representative of primary caregivers in this study) 88-92% own a smartphone and ~99% own a cellphone.[25] Many technology-based mental health resources (e.g., mHealth) are effective, practical, desired by patients and providers, and available at low cost.[26–31] Prior work by our team and others suggests that mHealth has tremendous potential to positively affect homework use and adherence and resultantly, treatment efficiency and effectiveness.[32,33] Providers and patients strongly support the concept of using an mHealth app to improve homework implementation. Providers desire automated reminders, built-in rewards systems, data management, tracking, and summaries, and rationale and implementation instructions. Patients desire customizable avatars, incentives and rewards (e.g., levels, points), reminder notifications, instructions and rationale explanations, and data transfer between youth, caregiver, and provider accounts.[24]

mHealth solutions to improve access and quality of care are widely investigated and effective in facilitating behavior change.[27,34–36] As noted in recent reviews, some mHealth resources include features that can support homework (e.g., voice and SMS reminders and feedback, self-monitoring and assessment, modules and activities that can be used to facilitate between-session practice), but little emphasis has been placed on their role in affecting use and adherence.[32,33] Some mHealth apps with homework -specific resources have been developed with positive preliminarily effects (e.g., "PE Coach" for PTSD; "Challenger" for social anxiety; "Get Happy" for depression).[37–42] However, these were designed mainly for adult patients and data on their ability to explicitly target provider and use and patient adherence to homework is limited. It would be beneficial to develop and test an mHealth homework resource for youths and caregivers with a broad symptom focus.

3.2 Adhere.ly's initial conceptualization was informed by semi-structured qualitative interviews with 21 national trainers in Trauma Focused Cognitive Behavioral Therapy (TF-CBT) and 15 youth/caregiver TF-CBT patients. These interviews explored potential mHealth solutions to barriers to implementing homework during youth mental health treatment. Results suggested that many providers struggle to consistently develop, assign, and assess homework exercises with their patients, many of whom have difficulty remembering to practice skills in a correct and timely way that fosters adequate learning. Trainers and patients were generally positive about the potential for mHealth to improve the implementation of homework and provided suggestions for mHealth solutions in terms of functionality and user experience.[24]

4.0 Study Intervention

4.1 We designed Adhere.ly as a simple, HIPAA compliant, web-based application to help mental health providers implement homework during CBT with children with elevated PTSD, anxiety, and/or depression, and their caregivers. The three major components of Adhere.ly help providers to (1) **Practice** interactive, digitized CBT exercises with patients in-session; (2) **Remind** patients to practice CBT exercises for homework, and (3) **Review** homework during the next session. These functions are accessible via tabs on the left side of the site, as displayed in Figure 1.

Figure 1

The **Practice** component includes several brief interactive, digitized CBT exercises for providers to practice with patients in-session within each of the following areas: relaxation, affect and emotion, cognitive coping, exposure, parent-child activities, enhancing safety, and parenting videos (Figures 2-4).

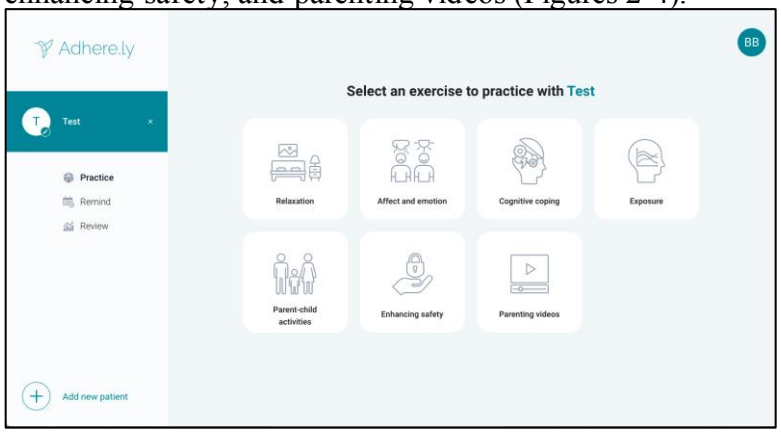

Figure 2

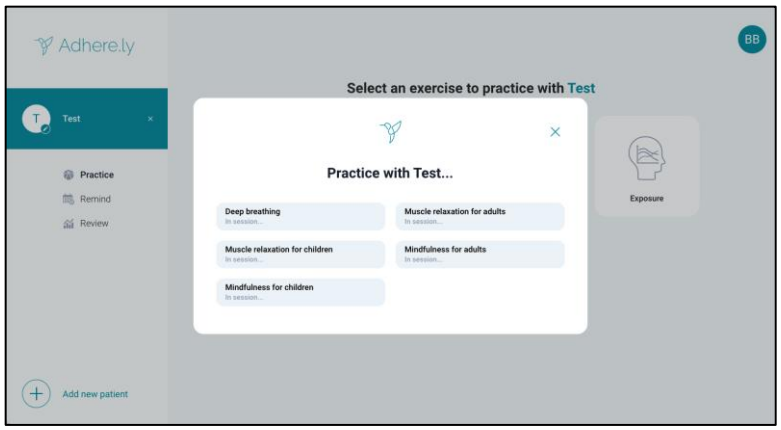

Figure 3

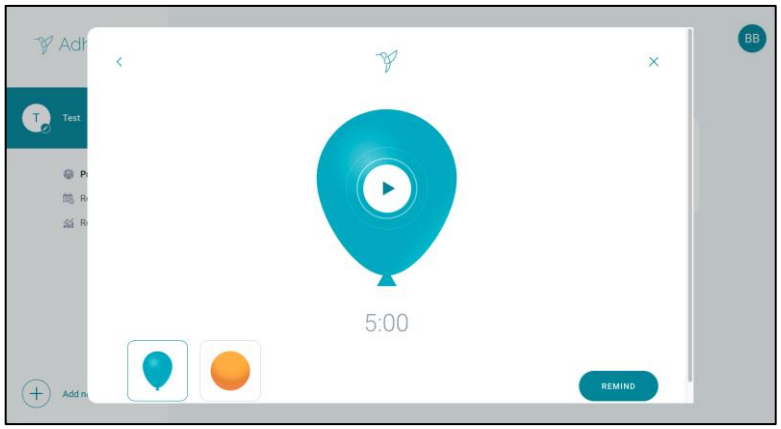

Figure 4

The **Remind** component enables providers to set automated text message/email reminders with editable default days/times, for patients to practice exercises between-session. This includes all exercises found in the **Practice** component as well as automated customizable reminders, encouraging messages, self-monitoring, and parenting exercises (Figures 5-6). Patients receive automated text message (or email) reminders during the following week on the specified days and times that contain links to the digitized exercises, which are opened and completed in the patients' smartphone or computer browser (i.e., no downloads or logins are required).

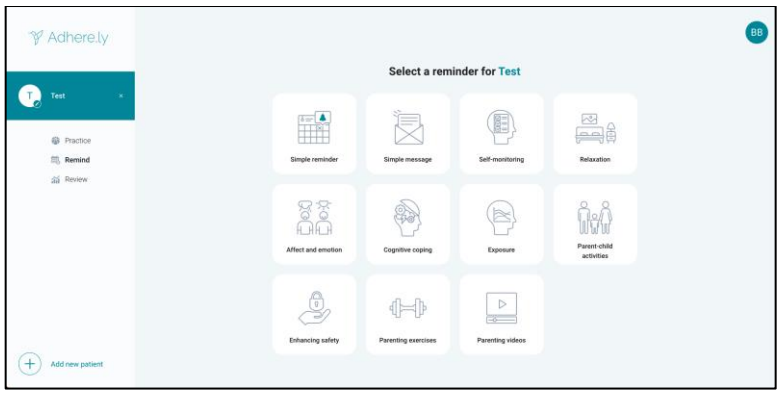

Figure 5

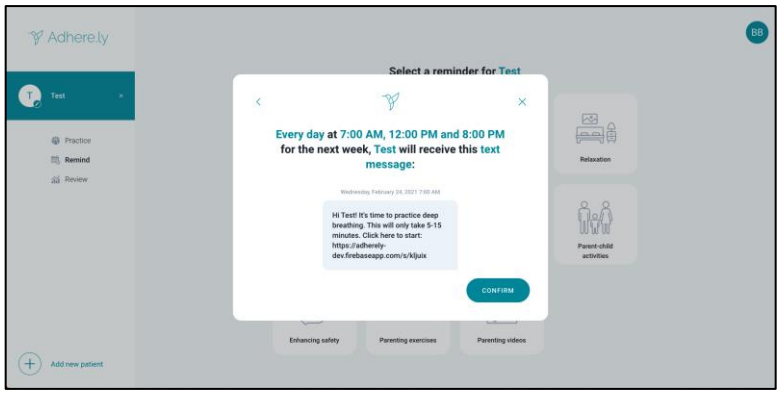

Figure 6

The **Review** component enables providers to view patients' homework completion and relevant data for certain exercises (e.g., self-monitoring ratings, anxiety ratings during exposure exercises; Figure 7).

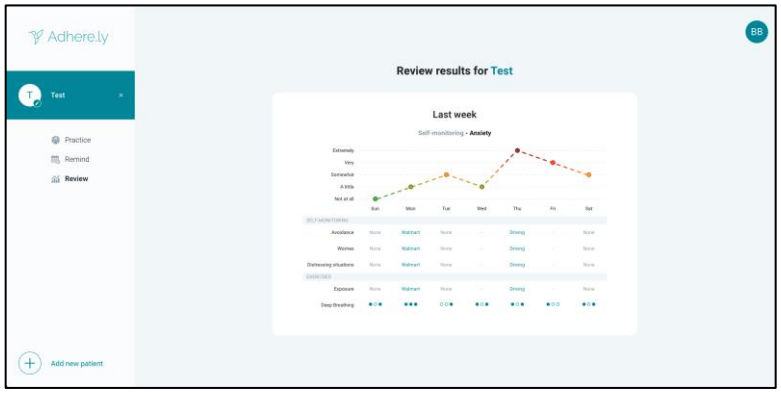

Figure 7

Adhere.ly is accessed by computer, tablet, and/or smartphone browser so it does not require any downloads by patients or providers. Patients do not create accounts or log in, and providers who choose not to create an account are still able to use the site with limited functionality. This functionality is limited in that it does not allow providers to save patient contact information (i.e., it must be entered every time a reminder is scheduled), does not allow providers to review homework results, and limits reminders to customizable reminders, encouraging messages, and self-monitoring and relaxation exercises (Figure 8).

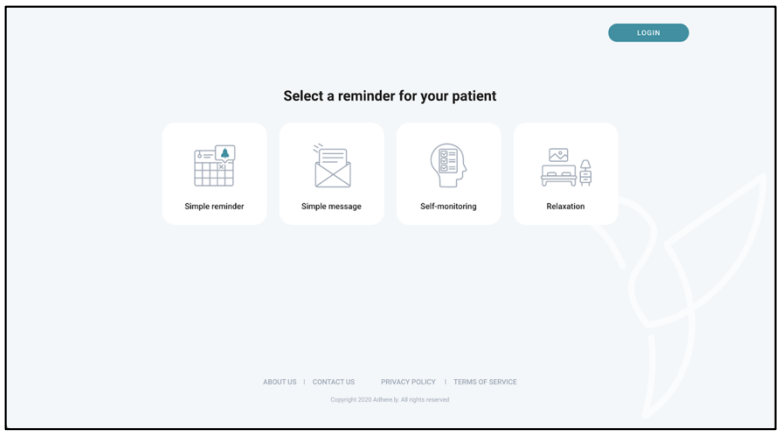

Figure 8

5.0 Procedures Involved

5.1 **Aim 1** of this study will use a randomized controlled trial design. The trial will include 60 community mental health providers randomized to deliver standard CBT (n=30) vs. CBT+Adhere.ly (n=30) to a total of 76 treatment-seeking youth ages 7-17 (n=38 per condition) with clinically elevated anxiety, depression, and/or PTSD, and their caregivers (n=38 per condition). Youth and caregivers will be referred and treated by providers. Study staff will facilitate web-based administration of baseline and 3- and 6-month post-baseline questionnaires with children and caregivers via REDCap. Treatment sessions may be audio recorded and uploaded to REDCap by providers and coded by study staff to assess provider assignment and assessment of homework. Families will have the option to allow providers to audio-record the youth's therapy sessions through the caregiver consent. Youth homework adherence will be assessed weekly on the day of their next session using a REDCap survey, a link to which will be sent via automated text-message and/or email reminders, or by telephone after 1 day of no response. Post-trial qualitative interviews will be conducted with ≤20 providers and ≤10 families.

Aim 2 of this study will use a mixed methods design and will include remote, 30-minute individual qualitative interviews with ≤10 community-clinic providers, ≤10 supervisors, and ≤10 senior leaders.

5.2

☒ Audio/Video Recording	☐ Psychophysiological Recording
☒ Behavioral Interventions	☐ Record Review - Educational
☒ Behavioral Observations and Experimentations	☐ Record Review - Employee
☐ Deception	☐ Record Review- Medical
☐ Focus Groups	☐ Record Review - Other
☒ Interviews	☐ Specimen Collection or Analysis
☐ Investigational Device – Non-Significant Risk (e.g. Mobile Applications)	☒ Surveys and/or Questionnaires
☐Psychometric Testing	☐ Other Social-Behavioral Procedures

Recruitment of Providers and Orientation to Study Procedures
We will recruit 60 master's-level mental health providers by leveraging established research-practice partnerships with mental health clinics and centers in Florida (see attached Letters of Support). Providers will be contacted by study staff via telephone and/or email to inform them about the study and inquire about their interest in participating. Providers who express interest in participating in the study will be scheduled for a 30-60-minute, televideo-based consent and training process with study staff to discuss the study, referral procedures, audio recording sessions, and uploading recordings to REDCap. Signed informed consent from providers will be obtained by study staff via REDCap e-Consent. Afterwards providers will complete a demographics questionnaire and the Attitudes Toward Homework Questionnaire (ATHQ).[15]

Recruitment of Youth and Caregiver Patients
We will recruit 76 treatment-seeking youth ages 7-17 with clinically elevated anxiety, depression, and/or PTSD, and their primary caregivers (n=76). Families will be referred and by providers following their initial intake session with that provider. We will ask providers to refer 4-5 families to maximize the likelihood of treatment completion with at least 3 families. Providers will receive automated weekly emails with reminders to make referrals and links to a REDCap referral form. Providers will also be able to provide referral information via telephone or email if preferred. Providers will be given informational cards with a QR code to a brief video with information about the study to show to families. If families express interest in the study, providers will assist them in completing the referral or obtain verbal consent to submit their referral information.

Upon receiving a referral, study staff will contact families within two working days to provide study information, assess eligibility, obtain signed informed consent from caregivers and assent from youth via REDCap e-Consent, and assist families in completing baseline assessments. Study staff will assess eligibility by: (1) administering a phone screen to the caregiver; and (2) emailing or texting families a link through the REDCap system to a survey that will include a brief demographic questionnaire, the Revised Children's Anxiety and Depression Scale-25 Child Version (RCADS-25-Y)[43], Child and Adolescent Trauma Screen - Youth Report (CATS-Y)[44], Revised Children's Anxiety and Depression Scale-25 Parent Version (RCADS-25-P)[43], and Child and Adolescent Trauma Screen - Caregiver Report (CATS-P)[44]. Families who are eligible, as indicated by a T-score ≥ 65 on the RCADS-25-Y and/or RCADS-25-P or total score ≥ 15 on the CATS-Y and/or CATS-P, will then provide informed consent and assent via REDCap e-Consent, and complete the remaining study baseline questionnaires.

Treatment
Providers will be randomly assigned to administer either CBT alone (n=30) or CBT+Adhere.ly (n=30). All providers will be asked to administer CBT as they usually would for each patient, either in-person or via telemedicine, with CBT+Adhere.ly providers integrating Adhere.ly into treatment with their families. To minimize risk of CBT alone (i.e., "control") providers being less motivated to refer cases, providers will be informed of their assignment only after their first study-eligible family has been enrolled. Each provider will be asked to treat at least 3 families over the course of 3 months. Providers will be asked to audio record their treatment sessions using either audio recorders provided by the study team, or audiorecording software on their computer, if preferred. Families will have the option to audio record the treatment sessions through the caregiver consent. Providers will be asked to upload those recordings to REDCap either weekly or bi-weekly. Providers will receive automated

weekly emails with a reminder to upload audio recordings and a link to a REDCap form for uploading recording. This form will ask the provider to enter their name, the name of the youth being treated, and the session number. Providers who have not uploaded a recording after 2 weeks will receive a follow-up phone call from study staff to provide reminders and assistance where needed.

Assessment Strategy and Measures

Trial questionnaires are shown in Table 1. Baseline and 3- and 6-month post-baseline questionnaires will be completed by families via REDCap surveys. Study staff will email or text families a link to the survey through the REDCap system and will be available to remotely assist families in completing questionnaires. Youth and caregiver questionnaires will be sent via separate links to allow older youth privacy. As stated previously, two youth (i.e., RCADS-25-Y and CATS-Y) and two caregiver questionnaires (i.e., RCADS-25-P and CATS-P) will be administered to screen potential participants for eligibility criteria and will be administered prior to obtaining informed consent. The informed consent document will specify that these data will be included with participants' study data if they are eligible and agree to participate or will not be included if they are ineligible or decide not to participate.

Table 1. Assessment Measures for Trial

Domain	Informant	Measure	Time Point		
			B	3M	6M
Demographics	Provider Youth Caregiver	Provider Demographics Questionnaire Families Demographics Questionnaire	✓		
Attitudes Toward Homework	Provider	Attitudes Toward Homework Questionnaire (ATHQ)[15]	✓	✓	
Youth Anxiety/Depression	Youth Caregiver	Revised Children's Anxiety and Depression Scale-25 Child Version (RCADS-25-Y)[43] Revised Children's Anxiety and Depression Scale-25 Parent Version (RCADS-25-P)[43]	✓	✓	✓
Youth PTSD	Youth Caregiver	Child and Adolescent Trauma Screen - Youth Report (CATS-Y)[44] Child and Adolescent Trauma Screen - Caregiver Report (CATS-P)[44]	✓	✓	✓
Youth Disruptive Behavior	Caregiver	Child and Adolescent Disruptive Behavior Inventory (CADBI)[45]	✓	✓	✓
Youth Quality of Life	Youth Caregiver	KIDSCREEN-10 Index Child and Adolescent Version (KIDSCREEN-10-Y)[46] KIDSCREEN-10 Index Parent Version (KIDSCREEN-10-P)[46]	✓	✓	✓
Caregiver Anxiety	Caregiver	Generalized Anxiety Disorder-7 (GAD-7)[47]	✓	✓	✓
Caregiver Depression	Caregiver	Patient Health Questionnaire-8 (PHQ-8)[48]	✓	✓	✓
Therapeutic Alliance	Youth Caregiver	Working Alliance Inventory - Short Revised - Client Version (WAI-SR-Y)[49] Working Alliance Inventory - Short Revised - Client Version (WAI-SR-P)		✓	
Treatment Satisfaction	Youth Caregiver	Child/Adolescent Satisfaction Questionnaire (CASQ-Y)[50] Caregiver Satisfaction Questionnaire (CSQ-P)[51]		✓	

Note. B=Baseline; 3M=3-Month Follow-Up; 6M=6-Month Follow-Up.

Youth Homework Adherence, Provider Homework Use, and Treatment Fidelity

Youth homework adherence will be assessed weekly on the day of their next session using a REDCap survey, a link to which will be sent via automated text-message and/or email reminders, or via telephone by study staff after 1 day of no response. The first 4 items of the Homework Rating Scale II (HRS II) will be used to measure homework adherence.[52] Session audio recordings will be observationally coded by independent coders blinded to study aims. Provider adherence and competence in reviewing, designing, and assigning homework (i.e., homework use) will be assessed using the Homework Adherence and Competence Scale (HAACS).[53] Provider fidelity to the CBT treatment model will be assessed by coding a randomly selected 20% of session audio recordings using the Cognitive Behavioural subscale of the Comparative Psychotherapy Process Scale (CPPS-CB).[54] Provider general therapeutic and CBT-specific skills to appropriately deliver CBT will be assessed by the Assessment of Core CBT Skills (ACCS).[55]

Post-Trial Qualitative Interviews

Study staff will invite up to 20 providers (≤10 of whom that referred families and ≤10 of whom did not refer families to the study) and 10 randomly selected youth/caregiver patient dyads to participate in remote, ≤ 30-minute, individual qualitative interviews. Participants will be recruited via telephone by study staff and scheduled for an interview. Informed consent from providers and caregivers, and assent from youth to participate in these interviews will have been obtained by study staff during the initial consent process for the trial. Study staff will conduct semi-structured interviews during which interviewees will be asked to describe their experience with and/or reactions to the trial and each component of Adhere.ly, ranging the overall "look and feel" of the user interface to ease of navigation, with the goal of identifying barriers/facilitators relating to use. Interviewees will also be asked to complete the System Usability Scale[56] via REDCap survey to provide quantitative data on Adhere.ly's usability.

Qualitative Interviews to Assess Implementation Strategies
Study staff will invite ≤10 providers, ≤10 supervisors, and ≤10 senior leaders (e.g., Directors) from local community-based clinics to participate in remote, 30-minute, individual qualitative interviews to assess strategies for Adhere.ly's implementation. Potential participants will be contacted by telephone and/or email, informed about the study, invited to participate, and scheduled for an interview. Study staff will obtain verbal informed consent and begin interviews with an overview of the benefits of homework, its underutilization, and barriers to use and adherence. Study staff will provide participants with an overview of Adhere.ly and access to the app to become familiar with it. Study staff will then administer a semi-structured interview guided by the Modified Consolidated Framework for Implementation Research (mCFIR) domains relevant to this implementation (i.e., intervention characteristics, outer settings, inner settings, end-user characteristics, and process of implementation).[57,58]

Local Site Documents (See Uploads):

A. Provider Demographics
B. Patient Referral Form
C. Phone Screen
D. Screening Questionnaires
E. Trial Measures
F. Post-Trial Qualitative Interviews and SUS
G. Implementation Strategies Interviews

5.3 The standard of care procedures for children with clinically elevated anxiety, depression, and PTSD is traditional CBT from their mental health provider.

5.4 There are no additional foreseeable risks to the above procedures in need of further mitigation beyond those ordinarily incurred in working with this population. Standard operational procedures of clinics specify responsibilities for handling dangers to self and others, safety planning in the event of domestic violence, and reporting responsibilities in the event of a new episode of child abuse.

5.5 N/A
5.6 N/A
5.7 N/A

6.0 Data and Specimen Storage for Future Research

6.1 N/A
6.2 N/A
6.3 N/A

7.0 Sharing of Results with Subjects

7.1 Total scores on study questionnaires will be shared verbally by study staff with youth and caregivers upon request. Total scores will also be shared with providers upon request from providers and when permission to do so is granted by families as indicated on their informed consent form.

8.0 Study Timelines

8.1 **Aim 1.** Providers will participate in one 30-60-minute consent and training process and twelve ~60-minute therapy sessions per study case. Study referral procedures will take an additional 5-10 minutes per patient. An additional 5 minutes per patient, per session will be required to upload audio recordings. Providers who participate in post-trial qualitative interviews will spend an additional 30 minutes. In all, the total amount of time spent in the study will be approximately 40.5 hours over the course of 12 months, only 4.5 hours of which will be spent engaging in study procedures beyond their everyday practice.

Families will participate in a 15-minute eligibility screening and a 30-minute consent/assent process. Families will participate in twelve ~60-minute therapy sessions, engage in twelve ~10-minute homework assignments, and spend ~5 minutes each week completing homework assessments. Baseline, 3-, and 6- month follow-up assessments will take ~30 minutes. Families who participate in post-trial qualitative interviews will spend an additional 30 minutes in the study. In all, the total amount of time spent in the study will be approximately 16.5 hours over the course of 6 months, only about 2.5 hours of which will be spent engaging in study procedures beyond the time they would have otherwise been receiving therapy from their provider.

Aim 3. Providers, supervisors, and senior leaders who participate in qualitative interviews to assess implementation strategies will spend 30 minutes in the study.

9.0 Inclusion and Exclusion Criteria

9.1 **Aim 1**.
Providers: English-speaking, mental health providers who have obtained at least a master's degree in social work, counseling, clinical psychology, or related field; carry active child mental health treatment caseloads; and have a laptop, tablet, or smartphone with internet access.
Youth: English-speaking youth ages 7-17 years with clinically elevated anxiety and depression as indicated by a T-score ≥ 65 on the RCADS-25-C and/or RCADS-25-P or total score ≥ 15 on the CATS-Y and/or CATS-P; and have a laptop, tablet, or smartphone with internet access.
Caregivers: English-speaking, adult (≥18 years old) caregivers of a youth who meets eligibility criteria and have internet and smartphone access.

Aim 2. English-speaking, adult (≥18 years old) mental health providers, supervisors, and senior leaders in Florida.

9.2 Youth with self- or caregiver-reported (1) active psychotic symptoms (e.g., hallucinations, delusions) or (2) significant cognitive disability, developmental delays, or pervasive developmental disorder.

9.3 Families will be ineligible to continue if there is a discontinuation or interruption of CBT treatment with participating provider. If a family changes therapists to a provider enrolled in the study, they will be able to participate with the new provider but will be re-consented to confirm that they still want to participate with the new provider and will be notified that their baseline questionnaire data will be maintained to avoid the unnecessary burden of collecting those data a second time.

9.4 We will be including employees as participants.

10.0 Vulnerable Populations

10.1 This study will involve youth ages 7-17. Informed consent will be obtained from parents or legal guardians, who also will be participants in the study. Assent will be obtained from all youth. Youth and their caregivers will be informed that their information will remain confidential and their decision to participate in the study will not affect the quality of care that they would have otherwise received from their provider.

11.0 Local Number of Subjects

11.1 **Aim 1.** We will recruit 60 providers, 76 youth patients, and 76 caregivers. N=212.

Aim 2. We will recruit ≤10 community-clinic providers, ≤10 supervisors, and ≤10 senior leaders. N=30.

12.0 Recruitment Methods

12.1

☒ Email	☐ Online/Social Media Advertisement
☒ Flyer	☐ Record Review
☐ Letter	☐ SONA
☐ News Advertisement	☒ Other

12.2 **Aim 1. Providers** will be recruited by leveraging established research-practice partnerships with mental health clinics and centers in Florida. Providers will be contacted by study staff via telephone and/or email to inform them about the study and inquire about their interest in participating. **Families** will be referred and by providers following their initial intake session with that provider. We will ask providers to refer 4-5 families to maximize the likelihood of treatment completion with at least 3 families. Providers will receive automated weekly emails with reminders to make referrals and links to a REDCap referral form. Providers will also be able to provide referral information via telephone or email if preferred. Providers will be given informational cards with a QR code to a brief video with information about the study to show to families. If families express interest in the study, providers will assist them in completing the referral or

obtain verbal consent to submit their referral information. Upon receiving a referral, study staff will contact families within two working days to provide study information, assess eligibility, and obtain informed consent/assent.

Aim 2. We will leverage established research-practice partnerships Potential participants will be contacted by telephone and/or email, informed about the study, invited to participate, and scheduled for an interview.

12.3 We will emphasize and remind families that their decision to participate in the study will not affect the quality of care that they would have otherwise received from their provider.

13.0 Withdrawal of Subjects

13.1 If a participating provider decides to withdraw participation from the study, families being treated by that provider will also be withdrawn from the research without their consent and will revert to standard treatment. If a family changes therapists to a provider enrolled in the study, they will be able to participate with the new provider but will be re-consented to confirm that they still want to participate with the new provider and will be notified that their baseline questionnaire data will be maintained to avoid the unnecessary burden of collecting those data a second time.

13.2 Subjects who withdraw will continue to receive the same standard of care from their mental health provider.

14.0 Risks to Subjects

14.1 Physical, psychological, social, cultural, financial, and legal risks, and risks to privacy and/or confidentiality associated with this research are minimal because the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily lives of the general population or during the performance of routine physical or psychological examinations or tests.

These include:

1. Possible breach of patient privacy and/or confidentiality
2. Possible breach of the security of patient and provider online data
3. Possible patient discomfort due to completing psychological questionnaires
4. Possible patient and provider discomfort due to having therapy sessions audio recorded

14.2 N/A
14.3 N/A

15.0 Potential Benefits to Subjects or Others

15.1 Potential direct benefits to participants assigned to the CBT+Adhere.ly condition include access to a clinically useful health technology resource, gains in knowledge and skill, and better outcomes.

15.2 Researchers and the general scientific community will benefit from the knowledge gained from the study. This includes knowledge about how to design and implement a user-centered and stakeholder-informed program that supports patient and provider adherence to evidence-based practice as well as effective *vs*. less effective strategies for implementing health technology solutions that promote this adherence in mental health practice settings in the community.

16.0 Data Management and Confidentiality

16.1 The primary goal of the trial is to assess the feasibility of the proposed methodology, which will be analyzed using the RE-AIM framework.[59] Feasibility data will be examined using descriptive and inferential statistics where applicable for variables within each RE-AIM domain:

Reach: Number of potential providers and patients available for recruitment; percentage eligible/ineligible, invited, and enrolled (benchmark: 60 providers in months 1-2 of trial [15/month]; 76 patients in months 2-14 [5/month]); sample characteristics; reasons for ineligibility and varying levels of engagement; ambiguities regarding eligibility criteria.
Effectiveness: Attrition and related patient characteristics; adverse events; satisfaction; impact.
Adoption: Estimated number of settings for future trials; settings and stakeholder characteristics.
Implementation: Percentage of providers and patients who use the app (benchmark: 70%); average number of modules used by providers and patients (benchmark: 50%); percentage of session recordings uploaded (benchmark: 70%) and completed weekly HRS (benchmark: 70%); retention of patients at follow-up (benchmark: 70%); level of use and adherence; staff/provider/patient time commitments; patient retention; assessment time burden; completed assessments and missing items; broken/lost/stolen equipment; technical issues.
Maintenance: Clinical outcomes at 3- and 6-months post-baseline.

The secondary goal of the trial is to assess the preliminary effects of Adhere.ly. The small sample size prevents any conclusions about effectiveness; however, exploratory analyses will be conducted using repeated measures ANOVA to preliminarily assess-between group differences in clinical outcomes (i.e., anxiety, depression, PTSD, disruptive behavior) and study targets (i.e., homework use and adherence) across study time points. Further, we will examine relations among study variables (i.e., caregiver anxiety and depression, therapeutic alliance, satisfaction).

Qualitative Interview Data Analysis. Interview transcripts will be coded by trained study staff in NVivo using a hybrid inductive-deductive, consensus-based content analysis.[60–62] Aim 2 interviews will also be analyzed using the mCFIR tool.[58] Coders will meet regularly to ensure consistency with code definitions and resolve inconsistencies via discussion to achieve consensus. Data aggregation queries will be used to create case memos and assign ratings for mCFIR constructs. We will use the Expert Recommendations for Implementing Change (ERIC) matching tool to generate a list of potential future implementation strategies based on the results of Aim 2 interviews.[63]

16.2 All data collected during the trial will be securely stored in a REDCap database, including informed consent/assent documents, questionnaire data, and audio recordings. Data obtained from Adhere.ly platform for the purposes of this study will include names,

phone numbers, and email addresses, and usage data relating to providers practicing, assigning, and assessing exercises, and families completing those exercises. These data will be downloaded from Adhere.ly and merged with the data in REDcap. Only IRB-approved and trained study personnel will have access to the REDCap project and access will be limited to information and modules that are required for them to complete their assigned study-related tasks. All identifiers will be marked as such in REDCap and will not be included in the final exported dataset, which will instead include assigned ID numbers.

We will use the following security measures to protect data sources:

1. all research data exported from REDCap will include ID numbers only
2. the codes that link the name of the participant and the study ID will be kept confidential in REDCap
3. computers and servers containing data will be password-protected to prohibit unauthorized access
4. online survey data collection will be accessible only by IRB approved study staff with secure logins
5. Adhere.ly includes state-of-the-art technical infrastructure–including encryption and other software, security practices, and business operational practices to ensure compliance with all major governing legislation, including HIPAA
6. all study data will be kept on a secure, USF server

16.3 We will use the following quality assurance measures for subject recruitment, enrollment, enrollment targets, and for the validity and integrity of the data:

1. study staff will complete and maintain up-to-date CITI and GCP training
2. study staff will be trained and supervised weekly by the PI
3. Standard Operating Procedures (SOPs) will be used to train all study staff
4. a Manual of Procedures (MOP) and study checklists will be used to ensure fidelity to the study protocol
5. informed consent will be obtained and documented by study staff to provide an audit trail
6. any contact with study participants or potential study participants will be documented to provide an audit trail
7. participant screening, recruitment, enrollment and enrollment targets, and data collection will be tracked to provide weekly updates to the PI
8. assessment data will be entered directly by participants into REDCap
9. automated validity checks will be in place for any data collection
10. data checks for ranges, cross-validity, and completion will be completed proximal to data collection
11. collection of any study data will be documented by study staff to provide an audit trail
12. coders will be trained and appropriate measures will be used to assess interrater reliability
13. coders will be blinded to study aims and hypotheses
14. the USF Conflict of Interest (COI) Office will maintain and monitor study progress according to ongoing conflict of interest management plans to ensure compliance with all requirements

16.4 Identifiable information in this study will include provider, youth, and caregiver names, phone numbers, email addresses, and physical addresses. Human subjects research records, including the original signed and dated consent documents, will be stored for at least 5 years after study completion. Signed and dated HIPAA authorizations and consent documents that include HIPAA authorizations will be stored for at least 6 years after study completion. After this time data will be deleted from REDCap. Youth assessment data will be shared with caregivers and providers upon request, as stated in the consent.

16.5

☒Obtaining Signed Authorization	☐Waiver of HIPAA Authorization for Recruitment/Screening Purposes Only
☐Obtaining Online or Verbal Authorization (Alteration of HIPAA Authorization)	☐Waiver of HIPAA Authorization for Entire Study
☐Data Use Agreement	☐Business Associate Agreement

Youth PHI that will be disclosed to providers will include total scores on questionnaires if families indicate their permission to do so on the consent form. Youth PHI that will be obtained from providers will include names, session dates, audio recordings of sessions, telephone numbers, and email addresses. We will document in REDCap events where PHI is disclosed or obtained.

17.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

17.1 The questionnaires used in this study are widely used and validated mental health instruments that can cause minor discomfort, particularly questions about prior traumatic events (e.g., the CATS). Participants will be informed that they can discontinue at any time and the PI, a licensed psychologist, will be available to speak with participants to address and resolve any issues relating to discomfort.

17.2 N/A

18.0 Provisions to Protect the Privacy Interests of Subjects

18.1 All research activities will be conducted over web-based surveys or telephone by IRB approved study staff located in a secure and private location. Subjects' assessment results will only be shared with their mental health provider if they indicate their permission when providing consent.

18.2 Study participants will provide informed consent or assent. We will not access any previously existing records.

19.0 Compensation for Research-Related Injury

19.1 N/A

20.0 Subject Costs and Compensation

20.1 Providers and families who participate in this study will have internet and

smartphone access, so we anticipate that they will have data and SMS plans that will allow them to participate without any additional costs. However, there is the small risk that some participants may exceed their monthly data or SMS limits during this study, resulting in additional costs for which they will be responsible. This risk will be discussed during the informed consent process.

20.2

☐No Compensation	☐Tokens (pens, food items, etc.)
☒Financial Compensation (cash, gift cards)	☐Other
☐Course Credit (i.e. extra credit, SONA points)	

Aim 1. Providers will receive a $50 eGift card after each family enrolls/consents into the study, in compensation of their time. When a family transfers to a new study provider, that study provider will be compensated with a $50 egiftcard. Currently enrolled providers will not be re-consented but will be contacted to be updated with the changes in compensation. Families will be sent eGift cards after the completion of each study assessment: $20 for baseline assessments, $20 for 3-month follow-up assessments, and $30 for 6-month follow-up assessments. In addition, participants who participate in individual qualitative interviews will be compensated $20 eGift card following completion of the interview.

Aim 2. Participants will receive a $50 eGift card following completion of the interview.

21.0 Consent Process

21.1

☒Obtaining Signed Consent (Subject or Legally Authorized Representative)	☐Obtaining Consent Online (Waiver of Written Documentation of Consent)
☐Obtaining Signed Parental Permission	☒Obtaining Verbal Consent (Waiver of Written Documentation of Consent)
☒Obtaining Signed Assent for Children or Adults Unable to Consent	☐Waiving Consent and/or Parental Permission (Waiver of Consent Process)
☐Obtaining Verbal Assent for Children or Adults Unable to Consent	☐Waiving Assent/Assent is Not Appropriate

21.2 **Aim 1**. The project coordinator will obtain signed informed consent from providers via REDCap e-Consent during a 30-60-minute, televideo-based consent and training process. We will ensure that providers understand all aspects of the study and consent form, and adequate time will be provided for questions relating to referral procedures, audio recording sessions, and uploading recordings to the study server. We will be conducting post-trial interviews with up to ≤20 providers, ≤10 of whom that referred families and ≤10 of whom did not refer families to the study. The trial consent form will also inform providers in the CBT+Adhere.ly that they may be asked to participate in post-trial qualitative

interviews if they participate. Currently enrolled providers will not be re-consented, but we will obtain verbal consent from 10 providers who were not in the CBT+Adhere.ly group to participate in post-trial interviews. To minimize the possibility of coercion or undue influence we will emphasize that declining to participate in the study will not influence their employment.

The project coordinator will obtain signed informed consent from caregivers and assent from youth via REDCap e-Consent during a 30-minute televideo-based consent process. We will ensure that providers understand all aspects of the study and consent form, and adequate time will be provided for questions relating to the assessment process over the course of the study. The consent form will include a field for caregivers to indicate their consent to have their child's total scores from questionnaires shared with their providers if requested and for their providers to audio record their child's therapy sessions. The consent form will also inform families that they may be asked to participate in post-trial qualitative interviews if they participate. To minimize the possibility of coercion or undue influence we will emphasize that declining to participate in the study will not influence the quality of care that they would have otherwise received from their provider. If a family changes therapists to a provider enrolled in the study, they will be re-consented to confirm that they still want to participate with the new provider and will be notified that their baseline questionnaire data will be maintained to avoid the unnecessary burden of collecting those data a second time.

Aim 2. The project coordinator will obtain verbal informed consent from providers, supervisors, and senior leaders prior to conducting interviews to assess implementation strategies. To minimize the possibility of coercion or undue influence we will emphasize that declining to participate in the study will not influence their employment.

21.3 This research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. If a youth participant turns 18 years old while participating in the study, study staff will obtain their consent verbally. The project coordinator will obtain verbal informed consent from providers, supervisors, and senior leaders prior to conducting interviews to assess implementation strategies. To minimize the possibility of coercion or undue influence we will emphasize that declining to participate in the study will not influence their employment.

21.4 N/A
21.5 N/A

21.6 This study will involve youth 7-16 years old. Signed assent will be obtained from all youth participants via REDCap e-Consent in addition to obtaining permission and informed consent from their caregivers. Signed permission and informed consent will be obtained from one caregiver even if the other caregiver is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

22.0 Setting

22.1 The research will be conducted via telephone, online, and in the USF Department of Psychiatry and Behavioral Neurosciences. Providers will practice and audio record sessions at their own clinic site, as normal.

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