UNIVERSITY of SOUTH FLORIDA
Research & Innovation

PROTOCOL TITLE:

Improving adherence to evidence-based practice using an innovative and easy-to-use health IT solution

PRINCIPAL INVESTIGATOR:

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VERSION NUMBER/DATE:

V10. February 13, 2024

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	July 8, 2021	We will conduct 90-minute focus groups instead of 60-minute individual interviews for Aim 1, resulting in a change in sample size from 60 to 72 for this aim; we revised the STTR Protocol, STTR Aim 1 Interviews Verbal Consent form, and STTR Aim 1 Focus Group Recruitment Email to reflect these changes; we updated the Aim 1 interview for focus groups; we uploaded Aim 2 trial questionnaires as separate word documents; we renamed documents to include the version number.	Yes
2	August 24, 2021	In addition to audio recording the focus groups for Aim 1, we will also screen-record. We revised the STTR protocol and STTR Aim 1 Focus Group Verbal Consent form to reflect these changes.	Yes
3	December 10, 2021	We revised the protocol to include new focus group recruitment strategy	No
4	January 13, 2022	We revised the protocol to include additional focus group strategy. We uploaded STTR Aim 1 Facebook Info Card for Patient and STTR Aim 1 Focus Group Facebook Recruitment Ad for Facebook recruitment.	No

5	January 24, 2022	Revised protocol to increase provider sample size to 30 and patient sample size to 60 Revised the following consent forms to update sample sizes: STTR Aim 2 Patients Trial Consent, STTR Aim 2 Providers Trial Consent	Yes
6	July 18, 2022	Revised protocol to include the re-consent procedure if a study client changes therapists, include option for families to be able to opt out of audio recording their therapy sessions and the Assessment of Core CBT Skills (ACCS) to assess provider's CBT delivery; increase provider sample size to 40 and client referral request to 3; and update provider compensation to be sent after family enrollment. We revised the STTR Aim 2 Patients Trial Consent, STTR Aim 2 Providers Trial Consent to reflect these changes; we updated STTR Aim 2 Info card for Providers, STTR Aim 2 Provider Patient Referrals Email, and STTR Aim 2 Audio Recordings Upload Email; we uploaded Study Introduction Script and STTR Aim 2 Trial ACCS.	Yes
7	September 20, 2023	Revised protocol to increase provider sample size to 50. We revised the STTR Aim 2 Patients Trial Consent and the STTR Aim 2 Providers Trial Consent to reflect these changes.	Yes
8	January 22, 2024	Uploaded STTR Aim 2 Trial Post-Implementation Client Interview Guide and STTR Aim 2 Trial Post-Implementation Therapist Interview Guide for post-implementation interviews.	No
9	February 13, 2024	Revised protocol to increase provider's post-implementation interview time to 45 minutes. Currently enrolled provider participants have already consented to the interview when they first consented/enrolled in the study, so they will not be reconsented, but study staff will verbally update them on the new time commitment. Therapists can choose to decline/withdraw if they want. Revised the following consent form to update new time commitment for newly enrolled participants: STTR Aim 2 Providers Trial Consent	Yes

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1.0 Study Summary

1.1

Study Title	Improving adherence to evidence-based practice using an innovative and easy-to-use health IT solution
Study Design	Randomized trial methodology with assessments
Primary Objective/Purpose	The purpose of this study is to expand 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 mental health treatment–to include new features and therapeutic exercises for adult patients, develop a plan for its implementation and sustainment, and preliminarily evaluate it by conducting a feasibility Optimization, Effectiveness, and Implementation (OEI) Hybrid trial.
Secondary Objective(s)/Purposes	N/A
Research Intervention(s)	Therapy
ClinicalTrials.gov NCT #	In progress.
Study Population	Masters-level mental health providers; Treatment seeking adults with anxiety and/or depression
Sample Size	N=282 Aim 1 focus groups: n=24 patients, 24 providers, 24 administrators Aim 1 survey: n=100 providers Aim 2 trial: n=50 providers; 60 adult patients
Study Duration for individual subjects	Aim 1 focus groups: 90-minutes each Aim 1 survey: 15 minutes Aim 2 trial providers: 28 hours over 9 months Aim 2 trial patients: 17 hours over 3 months
Study Specific Abbreviations/ Definitions	OEI=Optimization, Effectiveness, and Implementation I/S=Implementation/sustainment CBT=Cognitive Behavioral Therapy EBT=Evidence-Based Mental Health Treatment mCFIR=Modified Consolidated Framework for Implementation Research

2.0 Objectives

2.1

The purpose of this study is to expand 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 mental health treatment–to include new features and therapeutic exercises for adult patients, develop a plan for its implementation and sustainment, and preliminarily evaluate it by conducting a feasibility Optimization, Effectiveness, and Implementation (OEI) Hybrid trial.

Aim 1. Understand and prioritize key stakeholder goals, challenges, affordances, and constraints

We will use an exploratory sequential (qual→quant) mixed-methods design to conduct semi-structured focus groups (qual) with mental health patients, providers, and administrators and a survey (quant) with providers. We will conduct 4 focus groups per stakeholder group (patient, provider, administrator) and each focus group session will include up to 6 participants. We will enroll 100 providers to complete the survey. Analyses will inform the design of new Adhere.ly features and exercises and an implementation/sustainment (I/S) blueprint.

Aim 2. Optimize, preliminarily evaluate, and implement Adhere.ly in community practice settings

We will conduct a small-scale feasibility OEI Hybrid trial with 30 community mental health providers randomized to Cognitive Behavioral Therapy (CBT) alone (n=25) vs. CBT+Adhere.ly (n=25), and 60 treatment seeking and provider-referred adult patients with clinically elevated anxiety and/or depression (outcomes), which we will assess at baseline and 3-months post-baseline. We will assess homework use by providers and adherence of patients (targets) weekly via session audio recordings and patient-report. We will optimize new Adhere.ly features and exercises, and our I/S blueprint during the trial and assess implementation outcomes post-implementation.

2.2

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

3.0 Background

3.1

Homework is one of the most integral components of high-quality mental health treatment

Mental health disorders affect 1 in 6 youth and 1 in 5 adults in the U.S. and are associated with costly physical and behavioral health problems. The quality of services these patients receive *vs.* should receive is highly variable and characterized as a "quality chasm" by the IOM.[1] Homework, or between-session practice of skills learned during therapy, is one of the most integral, yet underutilized components of high-quality, evidence-based mental health treatments (EBTs) such as Cognitive Behavioral Therapy (CBT).[2,3] Homework exercises are assigned by providers in-session and completed by patients between sessions with the goal of practicing therapeutic skills in the environment

where they will be needed most.[4] Homework enables the generalization of skills and behaviors learned during therapy, facilitates treatment processes, provides continuity between sessions, allows providers to better grasp patients' learning, and strengthens that learning, leading to improved maintenance of treatment gains.[4–6] Meta-analytic and systematic reviews have shown that homework use by providers and adherence by patients predict increased treatment engagement, decreased treatment dropout, and medium-to-large effects on improvement in clinical outcomes (Cohen's *d*=.45-.77).[7–11] Simply put, 68% *vs*. 32% of patients can be expected to improve when therapy involves homework.[9]

Innovative solutions are needed to address barriers to the implementation of homework

Despite its many benefits, homework is implemented with variable effectiveness in "real world" clinical settings. Only 68% of general mental health providers and ~55% of family providers report using homework "often" to "almost always".[12,13] Providers report using homework in an average of 57% of sessions and only 25% of providers report using expert-recommended systematic procedures for implementing homework (i.e., specifying frequency, duration, and location; writing down homework assignments for patients).[14] A national survey revealed that 93% of mental health providers estimate rates of patient adherence to homework to be low to moderate,[12] and studies generally report low to moderate rates of patients' homework adherence.[15,16] There are many barriers to successful homework implementation. For example, many providers struggle to consistently develop, assign, and assess homework exercises with their patients, and many patients have difficulty remembering to practice skills in an correct and timely way that fosters adequate learning.[12–21]

Technology is ubiquitous and can address homework barriers, but more research is needed

Between 92-96% of adults aged 18-49 years own a smartphone and 99% own a cellphone.[22,23] Many health IT resources are effective, practical, desired by patients and providers, and available at low cost.[24] Prior work by our team and others suggests that health IT solutions have tremendous potential to positively affect homework use and adherence and as a result, the quality of mental health treatment.[21,25,26] Some existing health IT resources include features to support homework implementation (e.g., voice and SMS reminders and feedback, self-monitoring, assessment),[25,26] and some *m*Health apps with homework-specific resources have been developed with positive preliminary effects.[27–33] However, these resources are generally age-, disorder-, and treatment protocol-specific, and solely native app- based with limited interaction between patient and provider interfaces. Further, more data are needed to ensure that these resources have the ability to target homework use by providers and adherence by patients and be implemented in community practice settings.

Adhere.ly can address homework barriers and limitations of existing health IT resources

To address these limitations, our team of experts at Adhere.ly, LLC, USF, and the Medical University of South Carolina (MUSC), and Doxy.me, LLC developed Adhere.ly,

an innovative, state-of-the-art, and user-friendly solution to improve provider implementation and patient engagement in homework during EBTs. Adhere.ly is a free web-based platform with optional provider login, patient management features, and built-in therapeutic exercises (e.g., self-monitoring, relaxation, cognitive coping, emotion regulation, exposure therapy) for providers to introduce, practice, and assign as homework to patients. Patients receive SMS or email reminders with links to practice those exercises during the week on the days/times specified by providers, and providers are able to review patients' homework adherence and relevant data (e.g., self-monitoring ratings) on their dashboard. Adhere.ly was developed as a resource to improve homework implementation by providers and adherence in children and caregivers during treatment for childhood PTSD (F32 MH108250; K23 MH118482; PI Bunnell). One of the objectives of this NIMH Phase I STTR project, conducted in partnership with Adhere.ly, LLC, is to expand Adhere.ly to include additional features (e.g., more guidance for providers in-session) and therapeutic exercises that support a range of youth **and adult** EBTs.

3.2

Perspectives on homework barriers and mHealth solutions (NIMH F32 MH108250)

Adhere.ly's initial conceptualization was informed by semi-structured qualitative interviews with 21 national trainers in Trauma Focused Cognitive Behavioral Therapy (TF-CBT)[34] and 15 youth/caregiver TF-CBT patients. These interviews explored potential *m*Health 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 *m*Health to improve the implementation of homework and provided suggestions for *m*Health solutions in terms of functionality and user experience.[21]

Ongoing development and evaluation of Adhere.ly (NIMH K23 MH118482)

The current version of Adhere.ly was developed as a resource to improve homework implementation by providers and adherence in children and caregivers during treatment for childhood anxiety, depression, and PTSD. As such, the therapeutic exercises are mostly child focused.

Survey among community mental health providers

We recently conducted a survey among 277 community mental health providers who use telemedicine for about 25% of their caseload. The majority of respondents were master's- (64%) and doctoral-level (25%) providers working in individual practice (70%) and small clinic (18%) settings. Most providers reported treating adults (98%) with anxiety (95%), depression (87%), and PTSD (77%), and using cognitive-behavioral (82%) and interpersonal (52%) treatment approaches in their general practice. Almost half (41%) of providers reported assigning homework "never" to "sometimes," and the most common exercises assigned were mindfulness (78%), coping/emotion regulation (73%), relaxation (70%), interpersonal skills (56%), self-monitoring (56%), problem-solving (54%), and cognitive flexibility/reappraisal (51%).[35]

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 patients with elevated PTSD, anxiety, and/or depression. 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).

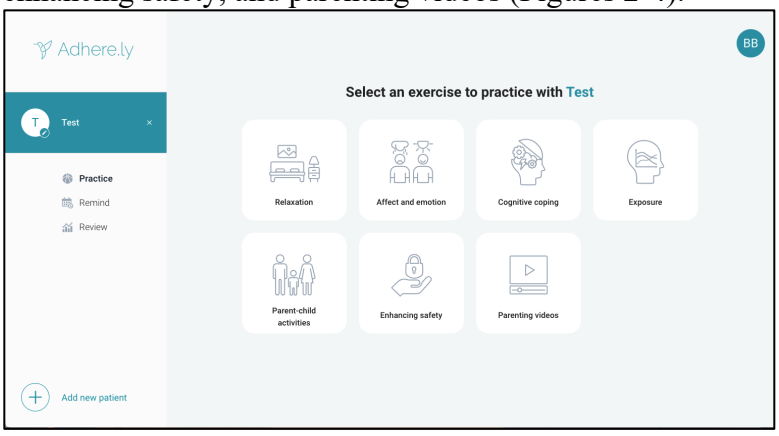

Figure 2

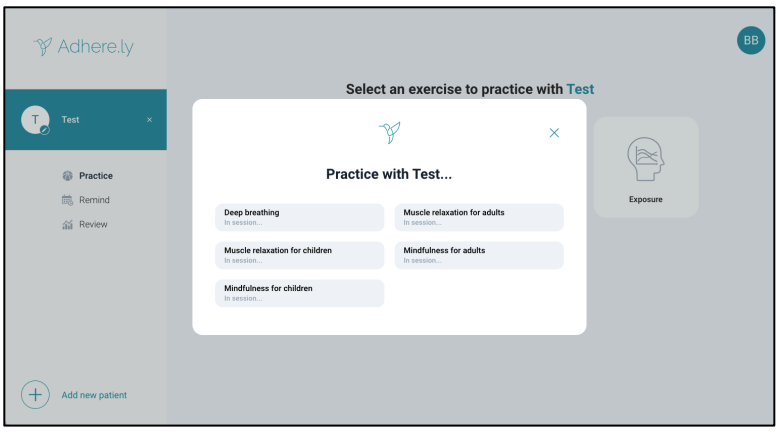

Figure 3

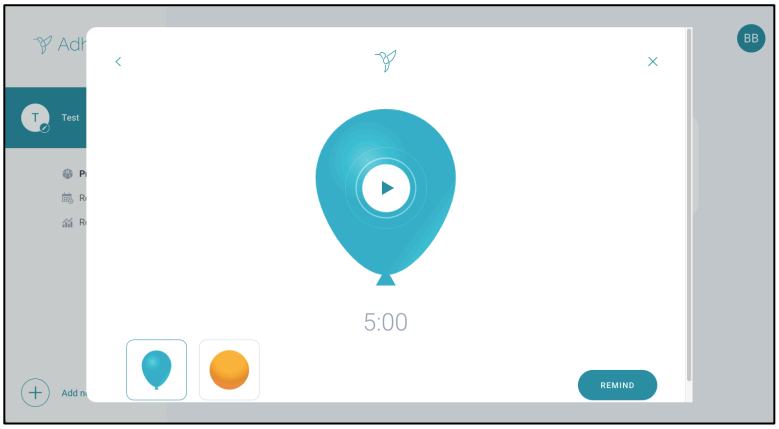

Figure 4

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).

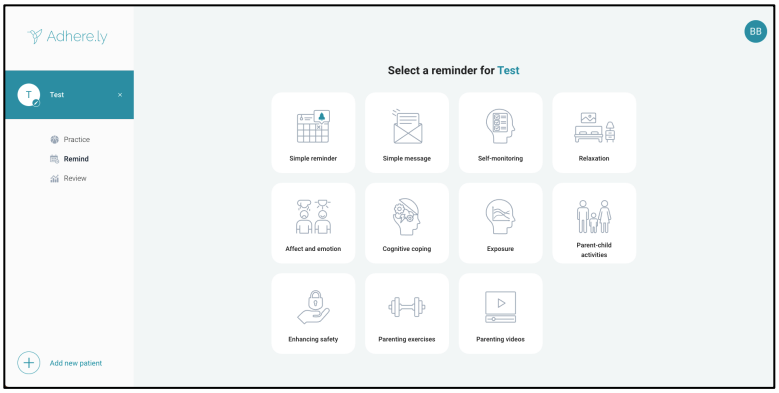

Figure 5

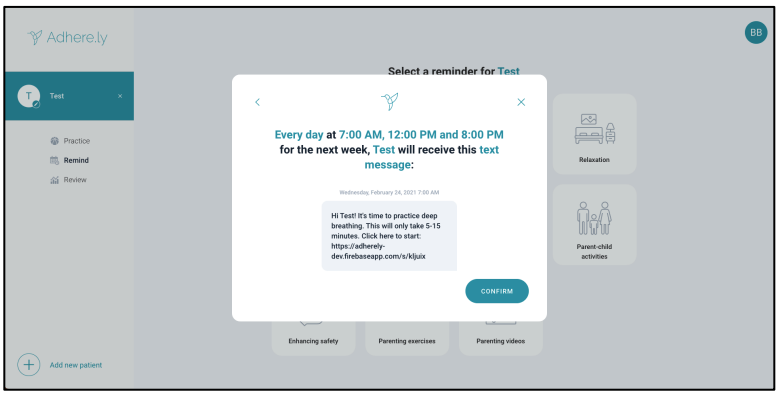

Figure 6

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).

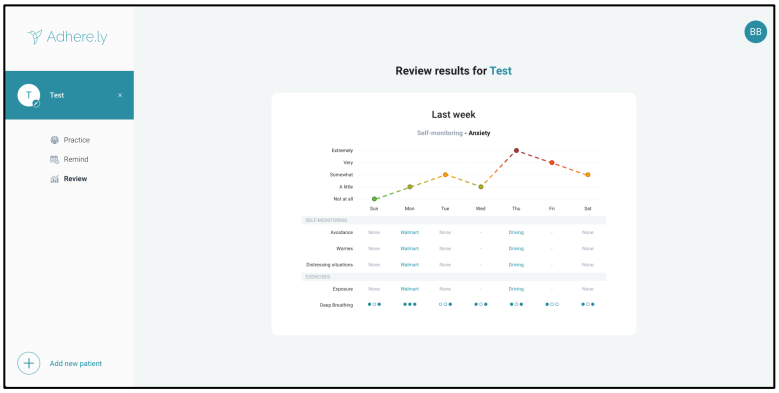

Figure 7

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).

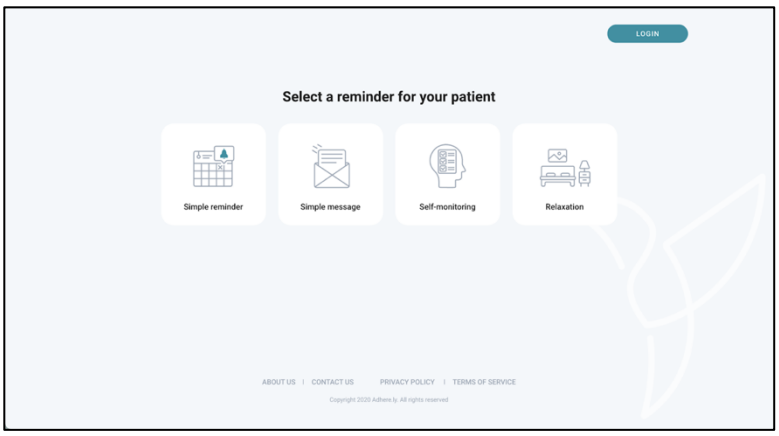

Figure 8

5.0 Procedures Involved

5.1

Aim 1. Understand and prioritize key stakeholder goals, challenges, affordances, and constraints

Aim 1 of this study will use an exploratory sequential (qual→quant) mixed-methods design to conduct semi-structured focus groups (qual) with mental health patients, providers, and administrators and a survey (quant) with providers. We will conduct 4 focus groups per stakeholder group (patient, provider, administrator) and each focus group session will include up to 6 participants. Half of the focus groups will consist of stakeholders from public healthcare institutions and the other half will consist of stakeholders from private healthcare institutions. We then will enroll 100 providers to complete the survey. Analyses will inform the design of new Adhere.ly features and exercises and an implementation/sustainment (I/S) blueprint.

Aim 2. Optimize, preliminarily evaluate, and implement Adhere.ly in community practice settings

Aim 2 of this study will use a randomized controlled OEI Hybrid trial design. The trial will include 50 community mental health providers randomized within their respective practice locations to administer CBT+Adhere.ly (n=25) vs. CBT alone (n=25) to a total of 60 treatment-seeking adult mental health patients with clinically elevated anxiety and/or depression–referred and treated by providers. Study staff will conduct pre- and post- implementation assessments remotely with providers and will facilitate web-based administration of baseline and 3-month post-baseline assessments with patients 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. Clients will have the option to allow providers to audio-record their therapy sessions through the consent. Patient homework adherence will be assessed weekly 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.

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

Aim 1. Understand and prioritize key stakeholder goals, challenges, affordances, and constraints

Study staff will invite up to 24 adult mental health patients, 24 providers, and 24 administrators to participate in remote (i.e., video conference or telephone), ≤90-minute, screen and audio-recorded, semi-structured focus groups to inform the design of new Adhere.ly features and exercises and an I/S blueprint. Study staff will email and/or call mental health providers and administrators registered with Doxy.me–who will be asked to refer adult patients–with information about the study and an invitation to participate (see attached Letter of Support from Dr. Welch at Doxy.me). Study staff will also post recruitment flyer on Facebook and submit research study into the Institute of Translational Health Sciences (ITHS) to recruit adult patients. Study staff will schedule an appointment to obtain verbal informed consent and begin focus groups, which will include basic demographic questions, an overview and brief demonstration of Adhere.ly, and will utilize the Modified Consolidated Framework for Implementation Research (mCFIR) domains relevant to Adhere.ly features and exercises and this implementation (i.e., intervention characteristics, outer settings, inner settings, end-user characteristics, and process of implementation).[36,37] Next, we will draw upon insights obtained from these focus groups and the literature on homework and processes-based CBT to develop a quantitative web-based survey that we will administer to 100 mental health providers, recruited via emails to providers registered with Doxy.me, to prioritize certain goals, challenges, features, and exercises.[38,39]

Aim 2. Optimize, preliminarily evaluate, and implement Adhere.ly in community practice settings

Recruitment of providers

We will leverage research-practice partnerships established in Aim 1 to recruit 50 master's-level mental health providers and will recruit additional providers via emails to mental health providers registered with doxy.me, if needed. 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 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).[12]

Recruitment of patients

We will recruit 60 treatment-seeking adults over 18 with clinically elevated anxiety and/or depression. Patients will be referred and by providers following their initial intake session with that provider. We will ask providers to refer 3-4 patients to maximize the likelihood of treatment completion with at least 3 patients. 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. If patients 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 patient within one working day to provide study information, assess eligibility, obtain signed informed consent from patients via REDCap e-Consent, and assist patient in completing baseline assessments. Study staff will assess eligibility by: (1) administering a phone screen to the patient; and (2) emailing or texting patient a link through the REDCap system to a survey that will include a brief demographic questionnaire, the Generalized Anxiety Disorder-7 (GAD-7) or Patient Health Questionnaire-8 (PHQ-8).[40–42] Patients who are eligible, as indicated by a score ≥ 10 on the GAD-7 or PHQ-8, will then provide informed consent via REDCap e-Consent, and complete the remaining study baseline questionnaires.

Treatment

Providers will be randomly assigned to administer either CBT alone (n=25) or CBT+Adhere.ly (n=25). 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 patients. 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 patient has been enrolled. Each provider will be asked to treat 3 patients 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. Clients will have the option to audio record the treatment sessions through their 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 recordings. This form will ask the provider to enter their name, the name of the patient being treated, the session number, and whether the session was conducted in-person or over telemedicine. 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-month post-baseline questionnaires will be completed by patients via REDCap surveys. Study staff will email or text patients a link to the survey through the REDCap system and will be available to

remotely assist patients in completing questionnaires. As stated previously, GAD-7 and PHQ-8 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
Demographics	Provider Patient	Provider Demographics Questionnaire Patient Demographics Questionnaire	✓	
Attitudes Toward Homework	Provider	Attitudes Toward Homework Questionnaire (ATHQ)[12]	✓	✓
Anxiety Severity	Patient	General Anxiety Disorder-7 (GAD-7)[40,41]	✓	✓
Depression Severity	Patient	Patient Health Questionnaire-8 (PHQ-8)[42]	✓	✓
Quality of Life	Patient	Health-Related Quality of Life (CDC HRQOL-14)[43]	✓	✓
Therapeutic Alliance	Patient	Working Alliance Inventory- Short Revised (WAI-SR)[44]		✓
Treatment Satisfaction	Patient	Client Satisfaction Questionnaire (CSQ-8)[45]		✓

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

Provider homework use, patient homework adherence, and treatment fidelity

Patient 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 patient homework adherence.[46] 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).[47] Provider general therapeutic and CBT-specific skills to appropriately deliver CBT will be assessed by the Assessment of Core CBT Skills (ACCS). [48]

Optimization

We will iteratively optimize Adhere.ly and our implementation strategies during the feasibility trial based on user data, error reports, support requests, and data from routine feedback interviews conducted by Adhere.ly, LLC. We will address unanticipated problems and opportunities encountered during implementation, remove unnecessary components and I/S strategies, and improve processes and functionality. We will develop a clear set of procedures for optimization and keep a log of all changes made for reporting purposes, consistent with the Trials of Intervention Principles outlined by Mohr and colleagues.[49]

Implementation

Pre-implementation assessments will take place during Aim 1. Study staff will conduct remote, ≤45-minute individual post-implementation interviews with ≤10 patients and ≤10 providers who participate in the CBT+Adhere.ly condition. Participants will be recruited via telephone by study staff and scheduled for an interview. Informed consent from providers and patients to participate in these interviews will have been obtained by study staff during the initial consent process for the trial. These interviews will use the mCFIR tool to assess perceptions about Adhere.ly's implementation and performance within each

of the mCFIR domains. To complement this evaluation of implementation processes, we will evaluate implementation outcomes with respect to Reach, Effectiveness, Adoption, Implementation, and Maintenance guided by the RE-AIM framework.[50,51] These data will be added to the robust mCFIR data to contribute to an overall summative evaluation.

5.3
The standard of care procedures for adults with clinically elevated anxiety and/or depression is traditional CBT from 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 and safety planning in the event of domestic violence.

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 patients upon request. Total scores will also be shared with providers upon request from providers and when permission to do so is granted by patient as indicated on their informed consent form.

8.0 Study Timelines

8.1
Aim 1. Adult mental health patients, providers, and administrators will participate in one ≤90-minute focus group. Providers will be invited to complete a ≤15-minute survey.

Aim 2. Providers will participate in one ≤60-minute consent and training process and twelve ~60-minute therapy sessions per study case. Study referral procedures will take an additional 5 minutes per patient. An additional 5 minutes per patient, per session will be required to upload audio recordings. Providers who participate in post-implementation interviews will spend an additional 45 minutes in the study. In all, the total amount of time spent in the study will be approximately 28 hours over the course of 9 months, only 4 hours of which will be spent engaging in study procedures beyond their everyday practice.

Patients will participate in a ≤60-minute eligibility screening, consent, and baseline assessment process. Patients will participate in twelve ≤60-minute therapy sessions, engage in twelve ~10-minute homework assignments, and spend ≤5 minutes each week completing homework assessments. 3-month follow-up assessments will take ≤30 minutes. Patients who participate in post-implementation interviews will spend an additional 30 minutes in the study. In all, the total amount of time spent in the study will be approximately 17 hours over the course of 6 months, only about 5 hours of which will be spent engaging in study procedures beyond the time they would have otherwise been receiving therapy from their provider.

9.0 Inclusion and Exclusion Criteria

9.1

Aim 1. English-speaking, adult (≥18 years old) mental health patients, providers, and administrators.

Aim 2.

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 adult mental health treatment caseloads; and have a laptop, tablet, or smartphone with internet access.

Patients: English-speaking, treatment seeking adults ≥18 years with clinically elevated anxiety and/or depression as indicated by a score ≥10 on the GAD-7 and PHQ-8; and have a laptop, tablet, or smartphone with internet access.

9.2

Patients with self-reported (1) active psychotic symptoms (e.g., hallucinations, delusions) or (2) significant cognitive disability, based on the phone screen.

9.3

Patients will be ineligible to continue if there is a discontinuation or interruption of CBT treatment with participating provider. If a patient 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.
N/A

11.0 Local Number of Subjects

11.1
N=282
Aim 1 focus groups: n=24 patients; 24 providers; 24 administrators
Aim 1 survey: n=100 providers
Aim 2 trial: n=50 providers; 60 adult patients

12.0 Recruitment Methods

12.1

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

12.2
Aim 1. Study staff will email and/or call mental health providers and administrators registered with Doxy.me–who will be asked to refer adult patients–with information about the study and an invitation to participate (see attached Letter of Support from Dr. Welch at Doxy.me). Study staff will also post recruitment flyer on Facebook and submit research study into the Institute of Translational Health Sciences (ITHS) to recruit adult patients. Study staff will then schedule an appointment to obtain verbal informed consent and conduct focus groups. We will recruit 100 mental health providers registered with Doxy.me via email to complete the web-based survey.

Aim 2. Providers will be recruited by leveraging research-practice partnerships established in Aim 1 and will recruit additional providers via emails to mental health providers registered with doxy.me, if needed. 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. **Patients** will be referred and by providers following their initial intake session with that provider. We will ask providers to refer 3-4 patients to maximize the likelihood of treatment completion with at least 3 patients. 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 the referral form. If patients 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 patient within one working day to

provide study information, assess eligibility, obtain signed informed consent from patients via REDCap e-Consent, and assist patient in completing baseline assessments.

12.3
N/A

13.0 Withdrawal of Subjects

13.1
If a participating provider decides to withdraw participation from the study, patients being treated by that provider will also be withdrawn from the research without their consent and will revert to standard treatment. If a patient 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 IT resource, gains in patient knowledge and skill, and better patient 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 IT solutions that promote this adherence in mental health practice settings in the community.

16.0 Data Management and Confidentiality

16.1

Aim 1 Data Analysis

Focus group transcripts will be coded by trained study staff in NVivo using a hybrid inductive-deductive, consensus-based content analysis,[52–54] and the mCFIR tool.[36,37,55] 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. Survey data will be analyzed to describe provider goals, challenges, affordances, and constraints. We will use the Expert Recommendations for Implementing Change (ERIC) matching tool to generate a list of potential implementation strategies for refinement.[56,57] We will synthesize qualitative and quantitative findings to prioritize new features, exercises, and I/S strategies.

Aim 2 Data Analysis

Feasibility

We will assess feasibility of the proposed trial methodology using the following benchmarks, which were informed by the sample size needed for hypothesis testing in Phase II and expert recommendations.[58–61]

Benchmarks: 50 providers will be enrolled in months 1-2 [20/month]); 60 patients will be enrolled in months 2-6 [8/month]); 70% of providers and patients will use Adhere.ly; 70% of session recordings will be uploaded; 70% of weekly HRS II assessments will be completed; 70% of patients will be retained at 3-month follow-up.

Evaluation

The small sample size prevents any conclusions about effectiveness; however, ANCOVA will be used to preliminarily assess-between group differences in clinical outcomes while co-varying for pre-treatment scores. ANOVA will be used to compare homework use and adherence. We also will preliminarily examine relations among study variables (therapeutic alliance, satisfaction).

Implementation

Interview transcripts will be coded by trained study staff in NVivo using the mCFIR

coding scheme developed during Aim 1. Data aggregation queries will be used to create case memos and assign ratings for mCFIR constructs, which we will examine between pre- and post-implementation using a modified CFIR matrix template. We will further synthesize qualitative with quantitative (i.e., mCFIR, RE-AIM) results to confirm and/or explain summative evaluation findings.

Table 2. RE-AIM outcomes

Dimension	Results
Reach	Number of potential providers and patients available for recruitment; percentage eligible/ineligible, invited, and enrolled; 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 Adhere.ly; average number of exercises used by providers and patients; percentage of session recordings uploaded; percentage of weekly HRS II completed; degree of use and adherence; provider/patient time costs; patient retention; assessment time burden; completed assessments; missing items; broken/lost/stolen equipment; technical issues
Maintenance	Clinical outcomes at 3-months post-baseline

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 patients 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, patient 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. Patient assessment data will be shared with 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

Patient PHI that will be disclosed to providers will include total scores on questionnaires if patients indicate their permission to do so on the consent form. Patient 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
N/A

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. 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 patients 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 participants will receive $50 and $15 eGift cards for completing focus groups and surveys, respectively.

Aim 2 providers will receive a $50 eGift card after each referred client enrolls/consents into the study, in compensation of their time. Patients will receive a $30 eGift card after completing baseline assessments and an additional $30 eGift card after completing 3-month post-baseline follow-up assessments, with a possibility of receiving a total of $60

in eGift cards. Participants who participate in post-implementation interviews will receive $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 2. The project coordinator will obtain signed informed consent from providers via REDCap e-Consent during a ≤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. The consent form will also inform providers that they may be asked to participate in post-implementation interviews if they participate in the CBT+Adhere.ly condition. To minimize the possibility of coercion or undue influence on providers we will emphasize that declining to participate in the study will not influence their employment. If a patient 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.

The project coordinator will obtain signed informed consent from patients 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 patients to indicate their consent to have their total scores from questionnaires shared with their providers if requested. The consent form will also inform providers that they may be asked to participate in post-trial qualitative interviews if they participate in the CBT+Adhere.ly condition. 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.

21.3

Aim 1. Study staff will obtain verbal informed consent from patients, providers, and administrators prior to conducting focus groups. Providers will indicate their consent to

participate in the survey by checking a box indicating their consent on the online consent form prior to completing the survey. To minimize the possibility of coercion or undue influence on providers 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
N/A

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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