PROTOCOL TITLE:

Evaluation of Text Message Engagement Support of Mindfulness Smartphone Applications

PRINCIPAL INVESTIGATOR:

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1.0 Purpose of the study:

The aim of this study is to assess the usability of two mindfulness smartphone applications (apps) and to evaluate whether text message support can promote engagement with those apps through a 4-week trial comparing support vs. no support. Part one of this study is to conduct usability testing to understand more about the acceptability and usability of these existing mindfulness apps in a population with depression and anxiety. The goal of usability testing is to identify any usability problems, provide information for future app development, and determine the participant's satisfaction with the apps. Participants will then be randomized to receive either engagement support or no support which will be delivered via text messaging, and will be randomized to use one of the two mindfulness applications for the 4 week period. Specific Aim 2.1 is to evaluate any differences on outcome measures between the mindfulness apps. Specific Aim 2.2 is to evaluate the differences of outcome measures between text message engagement support versus no support, regardless of the mindfulness app. For Aim 2.1, we predict that all mindfulness apps will be capable of leading to improvements on outcome measures. For Aim 2.2, we predict that the text message engagement support arm will engage more with the mindfulness app and will see greater improvements in outcome measures regardless of the mindfulness app.

2.0 Background / Literature Review / Rationale for the study:

Burden of Anxiety and Depression. Anxiety disorders are the most common mental illness in the United States, affecting 18.1% of adults. Mood disorders are the second most prevalent mental illness and carry the highest economic burden in the United States. Anxiety and depressive disorders are associated with significant economic and societal burden, including poor physical health, quality of life, and daily functioning. Additionally, anxiety and depressive disorders often co-occur. Depressive and anxiety disorders share common etiology and risk factors, such as genetic and environmental factors and have common cognitive, emotional, interpersonal, and behavioral factors that act to reinforce and maintain symptoms. Therefore, studies addressing the joint treatment of anxiety and depression are vital.

Technology-based interventions can combat depression and anxiety. In any given year, approximately 25% of the population in the United States meets criteria for a mental health disorder; however, only 70% of those individuals are receiving the appropriate treatment. Many barriers prevent people from receiving evidence-based treatment including costs, time, location, and stigma. To overcome these obstacles, alternative delivery methods, such as internet and mobile versions of evidence-based treatments, are increasingly being developed, studied, and used. Mobile interventions may be especially advantageous because they can be pervasive in people's daily lives. It is estimated that 95% of U.S. adults own a cell phone and 77% own a smartphone. Because of the increased availability of mobile phones, mobile health (mHealth) interventions are a growing area of research in mental health treatment. Internet, mobile, and other technology-delivered versions of evidence-based treatments for mood and anxiety disorders have been found effective and in some cases are as effective as face-to-face care. Supported interventions have been shown to have higher rates of adherence

compared to unsupported interventions. The predominant conceptual model underlying supported interventions is that of supportive accountability. Supportive accountability posits that support increases adherence through accountability to a coach who is seen as trustworthy, benevolent, and having expertise. Technological features that facilitate trustworthiness, benevolence, and expertise therefore have the potential to increase people's adherence to interventions and ultimately their benefit.

Mindfulness-based interventions for anxiety and depression. Mindfulness is the ability to intentionally and nonjudgementally observe thoughts, bodily sensations, or feelings in the present moment. Mindfulness is associated with improved health in the immune and autonomic nervous systems; increased of positive affect, life satisfaction, and emotion regulation; and reduced negative affect and mental illness symptoms. Furthermore, MBTs have demonstrated effectiveness in treating many disorders, including chronic pain conditions. In a 2016 meta-analysis, mindfulness-based interventions were shown to improve depression, anxiety, and well-being. While guided online mindfulness based interventions have been found to be more effective than unguided mindfulness interventions, little is known about which of these technology delivered interventions are more effective, what features are intuitive and easy to use, and what role supportive text messages play in continued engagement with technology delivered mindfulness based-interventions.

Therefore, the proposed project will evaluate the effectiveness of 2 apps that incorporate principles of mindfulness to improve symptoms in depressed and anxiety participants, and whether or not supportive accountability text messaging will improve adherence and symptoms. Finally, usability testing will be conducted to understand more about the differences in ease of use and intuitiveness of the smartphone mindfulness apps.

3.0 Inclusion and Exclusion Criteria:

Inclusion/Exclusion Criteria: The aim of the inclusion/exclusion criteria is to obtain a clinically representative sample of 40 adults with clinically significant levels of anxiety or depression.

Inclusion criteria:

(1) meet criteria for clinically significant distress caused by anxiety defined by a Generalized Anxiety Disorder-7 (GAD-7) greater than a 10 or clinically significant distress caused my depression defined by a Patient Health Questionnaire (PHQ-9) greater than 10

(2) 18 years of age or older;

(3) fluent in English;

(4) lives in the Chicago area and are able to attend and in person session;

(5) own an internet ready smartphone with data and text plans.

Exclusion criteria:

(1) have visual, hearing, voice, or motor impairment that would prevent completion treatment procedures;

(2) past or current diagnosis of a psychotic disorder, bipolar disorder, dissociative disorder, substance or alcohol abuse dependence, or other diagnosis for which participation in the trial would be dangerous;

(3) suicidal, defined as a 1 or higher on item 9 of the Patient Health Questionnaire (PHQ-9);

(4) adults unable to consent.

4.0 Sample Size:

We hope to recruit a sample of 40 participants. Given that there are two conditions based on the two different MBT mobile apps, this liberally allows 20 participants in each condition. For the 2 x 2 factorial randomized controlled trial, it is worth noting that our main comparison is the main effect of engagement support and thus we focused our power analysis on that comparison. A power calculation was run for a *t*-test on the change in GAD-7 over the time of the trial. Two samples of size 20 would provide 80% power to detect an effect size of 0.05.

5.0 Research Locations:

This study will only be conducted at one site: Northwestern University Feinberg School of Medicine in the Center for Behavioral Intervention Technologies (CBITs) in the Department of Preventative Medicine. Participants will be asked to attend one in-person visit in the lab space in CBITs. Northwestern University will be responsible for the IRB, study design, recruitment, consent, all study procedures, data management, and data analysis.

6.0 Multiple sites:

Northwestern University is the only site that is involved in this research study.

7.0 Reliance Agreements/Single IRB:

N/A

8.0 Procedures Involved:

This study is not funded by the NIH but does meet their definition of a clinical trial. Thus this study has been registered with Clinicaltrials.gov.

Procedure

Participants will attend one laboratory-based individual session in the Center for Behavioral Intervention Technologies (CBITs) at Northwestern University's Feinberg School of Medicine for consent, study onboarding, and usability testing. This session will be held in the usability room in CBITs, which is equipped with video equipment, desks, and software needed for usability testing. After this first session, all assessments will be

administered online via the Northwestern University Biomedical Informatics Center (NUBIC) secure online assessment platform (RedCap).

Inclusion and exclusion criteria will be assessed via a self-report RedCap survey. This intake survey should not take participants longer than 30 minutes to complete. If participants are eligible for the study, the participant will schedule the first in-person session to sign consent and complete the usability testing. Participants who are not eligible will receive referrals for treatment if needed. This research does not recruit exclusively for pregnant women and will not include research with neonates, prisoners, individuals under the age of 18, or cognitively impaired adults. It is possible that through recruitment, pregnant women will meet the criteria for this study. No additional risks are posed for pregnant women through participating in this trial.

Participants will attend the first session in CBITs to sign consent and engage in usability testing. This session will last anywhere from 60-90 minutes. Participants will complete demographics and baseline questionnaires during this visit. During usability testing, participants will be asked to engage with two widely available consumer mindfulness apps (Headspace; and Stop, Breathe & Think) to identify whether the apps improve knowledge about mindfulness and mental health, if the design promotes efficient and effective use with minimal guidance, if the design promotes memory of efficient use, the user satisfaction with the app, and the perception of the usability of the app. Usability testing will include the participant engaging with the app (opening the app, getting to a certain mindfulness tape, etc.) and answering questionnaires.

App Use: During first visit, participants will be randomized to a mindfulness app. Study staff will assist the participants in downloading the app to their personal phone, paying for the month subscription, answering any questions about the app, and providing instructions on how to use the app over the following month. Participants will be instructed to listen to one mindfulness meditation of their choosing a day for a month. Some apps offer added features like symptoms logging; participants will be informed that they can utilize these aspects of the app, however, it is not a required part of the study.

Stop, Breathe, Think is the second publically available app in the GooglePlay and iTunes store and contains mindfulness meditations and activities (i.e., deep breathing). Additionally, Stop, Breathe, Think also has the ability to track mental, physical, and emotional symptoms. Stop, Breathe, Think costs $9.99 for one monthly account, which will be reimbursed by the research team.

Headspace is also publically available on GooglePlay and iTunes. Headspace includes hundreds of themed guided meditations for a range of topics from stress to sleep. Headspace costs $12.99 a month and will be reimbursed by the research team.

Participants will then be randomized to either receive engagement support or no support which will be provided via text messaging, and they will be randomized to one of the two mindfulness apps to use over the 4-week trial. This will allow us to compare the difference in symptom reduction of depression and anxiety between the two mindfulness applications, and if engagement support improves outcomes. Participants will be asked to engage with the app every day over the four weeks. Mindfulness exercises within the app last anywhere from 2 to 10 minutes but participants could use multiple exercises per app session depending on their interest. At the end of each week, participants will be sent a

RedCap survey to complete consisting of questionnaires about app usage and mental health symptoms, which should take no longer than 30 minutes. The research team is not collecting any data from the 2 apps. In the engagement support group, participants will be sent text messages that will encourage use of the app through tips, reminders, and encouraging messages. The text message engagement support group does not require any additional effort for participants randomized to this group.

The interviews and questionnaires will generate a significant amount of data in video recording and textual formats. To analyze the data, all qualitative data from the usability testing session will be transcribed. Once the data is converted to textual format, we can undertake a standard form of qualitative analysis to identify emerging themes and directions in the data.

Measures

Semi-Structured Interview: Participants will complete a semi-structured interview that includes questions participants' technology use, how easy was it to use the app, how difficult was it to use the app, what parts were confusing, which app participants' like best, what would they change and keep about the app, etc.? This will be completed at the first visit.

Usability Testing: To effectively measure system usability of the mindfulness apps, participants will engage in the apps and will be objectively measured based on learnability, effectiveness, efficiency, errors, and memorability. Learnability is the ease with which the task is learned and will be objectively measure by timing how quickly the participant completes the task. Effectiveness is the successful performance of the tasks divided by the number of tasks attempted. Efficiency is measured after the task is learned and is measured by the speed the participant completes the task. Errors is measured by the number of times the participant incorrectly completes the task and how quickly the participant recovers from the errors. Memorability is how easy the participant can return to the system, and is measured by the failure rate on the second use.

Demographics Questionnaire: Participants will complete a questionnaire indicating demographic information including gender, race/ethnicity, age, education, employment, income, and marital status. This will be given at the first visit.

System Usability Scale (SUS): The SUS is a 10-item self-report instrument measuring a user's rating of a product's usability. This will be given at the first visit.

After-Scenario Questionnaire (ASQ): The ASQ is a 3-item self-report instrument measuring a user's satisfaction with a product. This will be given at the first visit.

Usefulness, Satisfaction, and Ease of Use Questionnaire (USE): The USE is a 30-item self-report instrument measuring a user's ratings of usefulness, satisfaction, and ease of use of a product. This will be given at the first visit.

Application Survey: Participants will complete a questionnaire that provides additional qualitative and quantitative information about the evaluation of the app. This will be given at the first visit.

Acceptance and Action Questionnaire (AAQ-II): The AAQ-II is a 7-item self-report instrument measuring psychological flexibility. This will be given at baseline, week 2, and end-point.

Five Facet Mindfulness Questionnaire (FFMQ): The FFMQ is a 39-item self-report instrument measuring the facet structure of mindfulness. This will be given at baseline and end-point.

Patient Health Questionnaire-9 *(PHQ-9):* The PHQ-9 a 9-item self-report instrument measuring depressive symptomology. This will be given at screening, baseline, week 2, and end-point.

Generalized Anxiety Disorder-7 *(GAD-7):* The GAD-7 is a 7-item self-report instrument measuring anxiety symptoms. This will be given at screening, baseline, week 2, and end-point.

Beck Anxiety Inventory (BAI): The BAI is a 21-item self-report instrument measuring anxious symptomology. This will be given at baseline and end-point.

Depression, Anxiety, and Stress Scale (DASS): The DASS-21 is a 21-item self-report instrument measuring depression, anxiety, and stress related symptomology. This will be given at baseline, weekly, and end-point.

The Rumination-Reflection Questionnaire (RRQ): The RRQ is a 25 item self-report instrument measuring rumination and reflection. This questionnaire will be given baseline and endpoint.

Perceived Stress Scale (PSS): The PSS is a 10-item self-report instrument used to measure the perception of stress. This questionnaire will be given at baseline and end-point.

Quality of Life Scale (QOLS): The QOLS is a 16-item measure of quality of life. This questionnaire will be given at baseline and endpoint.

Insomnia Severity Scale (ISI): The ISI is a 7-item self-report instrument measuring sleep quality and insomnia. This questionnaire will be given at baseline and endpoint.

App Usage and Satisfaction: Participants will complete a questionnaire assessing how many times they launched the app each day during the previous week, how much time was spent engaging in a guided mindfulness meditation, and how satisfied they were with the app overall.

Data Analysis

Goal 1 Analysis. Mixed methods data analysis will incorporate qualitative data from user feedback, quantitative data from the satisfaction, acceptability, and usefulness ratings, and video recordings from the usability testing. Although quantitative ratings can highlight possible usability concerns, qualitative data provides answers to why those features might cause problems in ways that can guide development. Qualitative data will be analyzed following a grounded theory approach in which results from the semi-

structured interview will be analyzed using a series of codes to determine patterns in topics related to user needs, concerns, and impressions. Grounded theory was selected because it is a useful methodology for determining common topics within qualitative data to inform future practices and research. Video recordings will address ease of use and be coded to determine three types of errors. First, navigation errors refer to instances when users cannot locate a function or have difficulty with aspects of the screen flow. Second, content errors refer to instances of problems due to labeling or information presented. Third, usage errors refer to improper tool use or data field entry. Qualitative and quantitative data will be integrated through linking categories identified through the grounded theory approach with ratings on features.

Goal 2 Analysis. To analyze the data, we will use a mixed methods data analysis to evaluate the effectiveness of the engagement support condition versus the control condition, using the different guided meditation apps as a potential moderator. We will also use overall satisfaction of the app identified in the usability testing as a covariate to determine if usability concerns relate to eventual benefit attained from a mobile app.

9.0 Incomplete Disclosure or Deception:

This study will not use incomplete disclosure or deception.

10.0 Recruitment Methods:

Our goal is to obtain an ethnically and racially diverse sample while recruiting people who may not seek traditional treatment resources. Internet-based advertising (craigslist, reddit, etc.) will ensure that recruitment reflects the growing numbers of people who seek help through the Internet and may not have resources available to them otherwise, thereby enhancing external validity. Eligible participants will be recruited using a mass-scale, ongoing recruitment campaign across mainstream Internet-based social media sites. This type of online outreach has been useful in recruiting in previous studies. Additionally, a recruitment email will be sent out to individuals on the Center for Behavioral Intervention Technologies (CBITS) Research Registry. Upon entry into the registry, members complete a short survey on demographics and basic technology use. This information will be used to target emails to the appropriate audience (i.e. based inside of Chicago, possession of a smartphone).

11.0 Consent Process:

Written consent will be obtained by the principle investigator or research assistant during the first session, at Northwestern University, Feinberg School of Medicine, in the Center for Behavioral Intervention Technologies (CBITs). The subject will be given a copy of the consent document to read and the app's privacy policy. Then, prior to the subject signing, the principal investigator or research coordinator will verbally explain the protocol and answer any of the subjects' questions. Subjects are explained the risks and benefits of the study and are asked to voluntarily participate. Participants are

informed that if they choose to not participate in this study, it will not affect the care they receive at Northwestern.

If the subject requires additional time to make a decision, they will be provided with a copy of the consent document to take home for consideration. Upon signing, the subject will receive a copy of the signed consent document.

12.0 Financial Compensation:

Participants will be compensated for their time: $30 at the usability session, $20 at endpoint, and $5 for the completion of each weekly assessment. Total possible reimbursement will be $65. Participants will be paid with an amazon credit.

13.0 Audio/Video Recording

This study will utilize video recording during the usability testing during the first session. Video recording is necessary during the usability testing to review and rate how the participant engaged with the app. Additionally, video recording is necessary to conduct a qualitative analysis of themes that emerge during testing session. The video recordings will be utilized for data analysis only.

14.0 Potential Benefits to Participants:

Participants may experience a reduction of symptoms as a result of their participation in this trial.

Assessment of Risk to Benefit Ratio. Given that the risks associated with participating are minor, and the potential benefits of mobile applications for depressed and anxious individuals are considerable, it is believed that the risks are justified.

15.0 Risks to Participants:

The proposed study poses minimal risks. Potential risks fall into four categories: (a) risks associated with the intervention; (b) risks associated with the research assessments; (c) risks associated with potential loss of confidentiality; (d) risks of worsening mental or emotional health. Each risk is addressed below.

(a) Risks associated with the intervention. Smartphone delivered mindfulness exercises have not been shown to cause any harm.

(b) Risks associated with the research assessments. The risks from completing the self-report measures are minimal. Research assessments include questions about depression, anxiety, and other mental and emotional problems. All research measures and

interviews are universally used and are not known to cause any harm. However, it is possible a participant may feel emotional discomfort as a result of answering questions about their mental health. In the informed consent, participants will be informed that their participation is voluntary. As such, participants will be informed that they do not have to answer any distressing questions.

(c) Risks associated with potential loss of confidentiality. There is a slight risk of loss of confidentiality. While the proper precautions will be taken to reduce the risk of loss of confidentiality, there are some risks the researchers cannot avoid. The research staff may have to break confidentiality if the participant expresses imminent threat to themselves or others. There is also a remote risk that research records will be subpoenaed by a court of law. All of these potential losses of confidentiality will be disclosed in the consent document. We will mitigate this risk by making certain that no information that identifies participants will be released without prior consent, except as specifically required by law. Resulting data will be kept in a locked, password protected database in which only the PI and research team have access. Finally, the research team has no control over the information that is collected by the apps. Participants will be informed that these apps may collect identifiable information about them and they will be given the opportunity to review the privacy policy of the app prior to consenting. The research team will have no access to the data collected by the apps. The app developers will not know that these individuals use of the app is a part of a research study, in order to protect information about their mental health.

(d) Risks of worsening mental or emotional state. Some participant may experience a worsening of depression and anxiety symptoms or other problems regardless of study participation. The development of suicidal ideation during the study is the most serious concern; however, these risks are inherent in a population with depressive and anxiety disorders. We do not predict worsening mental or emotional symptoms being a function of enrollment in this study. There are no specific criteria for removal of a patient from the study. A patient will be removed if continued participation is determined to constitute a danger to the patient's health or well-being by the PI based on input from the questionnaires. If the PI determines the patient must be removed from the study immediately, the patient will be removed and all appropriate referrals will be made. The IRB will be informed of any participant withdrawal from the study.

16.0 Provisions to Protect the Privacy and Confidentiality of Participants and the Research Data:

Data for all participants will be kept strictly confidential, except as mandated by law. Research material will be the following: 1) Questionnaires filled out by participants via RedCAP, a secure web-based system, and 2) qualitative data (video recordings) collected from the usability testing session. All research files are kept on secure, password protected departmental and medical school servers. All electronic data will be stored on secure servers behind firewalls meeting all security requirements of the medical school. All data will only be used for research purposes. Data collected from participants who are not eligible for the study will be deleted, however, record will be kept of how many individuals screen failed and the reason for screen fail. Only the research staff will

have access to individually identifiable private information about human subjects. The apps may collect identifiable information. The research team will not have access to this information and is not capturing any data from the app. Additionally, the app developers will not be aware that the participants are a part of a research study. Privacy policies will be uploaded to Supporting Documents in the IRB system. Self-report data will be de-identified upon entry and password-protected on the secure server of the Northwestern Feinberg School of Medicine Department of Preventive Medicine. This server is only accessible to staff with the credentials needed to access the network. Contact information for participants will also be entered on the secure departmental server in a separate database, using the unique participant ID number for identification in case the data needs to be linked to an individual and the hardcopy of the contact information is not at hand (as in the case of an emergency). Video data will be stored on secure servers. Transcriptions of the video recordings will only be available for coding by study staff. Any paper documentation (consents) is kept in locked file cabinets or a locked file room. Data will be kept for 7 years after the completion of the study. All data presentation will be of aggregate-level data; participants are never individually named. Individual participant's data may be reported, anonymously, to provide examples of how participants used the intervention.

17.0 Data Monitoring Plan to Ensure the Safety of Participants:

This study will be monitored by Stephen Schueller, PhD, and Elizabeth Adkins, MA. Dr. Schueller and Elizabeth will review all screening and baseline assessment data to evaluate the processes used to determine the safety of enrolling participants. Weekly and end-point data will also be reviewed for evaluation of the safety of the intervention and the procedures used to detect and respond to deterioration and/or suicidality. The researchers will closely monitor all incoming data, recruitment progress, and retention in assessments and treatment. The researchers will discuss responses to PHQ-9 and GAD-7 immediately after assessments should there be any concerns regarding participant safety or deterioration; otherwise, screening responses will be reviewed the same or next business day. Adverse events will be reported by the principle investigator to the Northwestern University's Institutional Review Board (IRB). While, Northwestern's IRB does not play an active role in monitoring data; IRB approval is necessary to conduct the proposed research, and thus the human subjects protections will be thoroughly examined for safety.

18.0 Data, and if applicable, Specimen Banking:

Not Applicable.

19.0 Data Sharing:

There will be no data sharing outside of our research team. Aggregate de-identified data from this study may be shared with the research community at large to advance science and health.

20.0 Qualifications to Conduct Research and Resources Available:

Personnel

1. Stephen Schueller, PhD (Principal Investigator): Dr. Schueller received his PhD in Clinical Psychology in 2011 from the University of Pennsylvania. While at the University of Pennsylvania, Dr. Schueller worked under the mentorship of Dr. Martin Seligman, He received training in CBT for depression at the University of Pennsylvania from Dr. Robert DeRubeis. Dr. Schueller continued to refine his CBT skills working with low-income and minority patients at San Francisco General Hospital during his clinical internship and postdoctoral fellowship at the University of California, San Francisco under the supervision of Dr. Ricardo Muñoz. In September 2012, he joined the faculty at Northwestern University as a Research Assistant Professor in the Department of Preventive Medicine at the Feinberg School of Medicine and a member of the Center for Behavioral Intervention Technologies (CBITs).
2. Elizabeth Adkins, MA (Research Assistant): Elizabeth received her Masters in Psychology from Boston University. While at Boston University, she worked on multiple depression studies under the supervision of Dr. Michael Otto. After graduating, she worked for two years as a research assistant in the department of psychiatry at Rush University Medical Center. At Rush, she coordinated multiple NIH and industry funded trials for post-traumatic stress disorder, social anxiety disorder, and generalized anxiety disorder. She is a doctoral student at Northwestern University, Feinberg School of Medicine, and is advised by Dr. Schueller in the Center for Behavioral Intervention Technologies.

Other Resources

Northwestern University, Feinberg School of Medicine, Department of Preventive Medicine: Preventive Medicine was ranked 4th of preventive medicine departments funded by NIH in 2012. It has a demonstrated track record of successful grant applications.

Facilities: The Department occupies 19,076 square feet of office on the 14th floor and 12,000 square feet on the 15th floor of 680 N. Lake Shore Drive of 680 N. Lake Shore Drive. The Department is fully linked to all University services via on-campus telephone system and hardwire computer networking services. The department also has one large conference room that seats up to 60 people for classes, seminars, and meetings, and four smaller conference rooms that seat up to 30 people for classes and meetings.

Computational Resources: Faculty and staff are supplied a personal computer and have access to a printer and scanner (available software includes SPSS/SAS, MS Office, Adobe, etc.). Faculty and trainees also have access to research databases, administrative support, hardware, and software assistance available directly within the Department. The Department has a secure server with data security features ensuring confidentiality of

participant data. All laptops are encrypted and the network has firewall protection. In addition, Northwestern's information technology program supports researchers with the software, hardware, and data storage and retrieval facilities to conduct large-scale projects.

Center for Behavioral Intervention Technologies: Provides consultation for development of technology assisted (e.g., web-based, mobile) behavioral interventions including assisting in early planning and design of the intervention, programming the intervention, and initial testing to ensure technical reliability. Expertise in developing behavioral intervention technologies and technology assisted assessment tools, establishing usability testing protocols, running usability testing for projects, creating secure data collection methods, and training and supervising clinicians for technology interventions.