PROTOCOL TITLE: Implementing mobile apps for depression and anxiety in a community services agency

PRINCIPAL INVESTIGATOR:

[redacted]

VERSION NUMBER: 1

VERSION DATE: October 9, 2017

Objectives:

Primary Aims

- Identify barriers and facilitators to IntelliCare app implementation for [redacted], a community mental health agency.
- Identify methods for tailoring the IntelliCare coaching protocol to fit within [redacted] clinician workflows.

Background:

There is tremendous need for behavioral health treatment, and care organizations find themselves unable to keep up with the demand. [redacted] is a community organization providing behavioral health services to >27,000 people annually throughout the [redacted] Like many community providers, [redacted] doesn't have the capacity to treat the large numbers of clients in need of services. Their counseling services often have waiting lists of 2+ months, and as they expand their in-home counseling services, staff need more sophisticated resources for delivering treatment remotely.

More than 50 efficacy trials have shown that mobile apps and web-based interventions are effective for delivering mental health treatment, and the Center for Behavioral Intervention Technologies (CBITs) has become a leader in the digital mental health field. The CBITs team developed IntelliCare, a suite of apps designed to promote coping skill acquisition. A field trial of 99 participants with elevated symptoms of depression or anxiety demonstrated substantial reductions in symptoms over 8 weeks (*p*s<.0001). In this trial, coaches monitored patient app usage, sent patients 2-3 texts per week and spent approximately 39 minutes on calls over the 8-week period. Clinicians at [redacted] have already begun recommending IntelliCare apps to patients, and both clinicians and administrators are now interested in implementing a coached version of IntelliCare.

There has not been a single published example of successful digital mental health intervention implementation. This may be due to the fact that these tools do not meet the needs of providers and have not been designed to fit into the context of the care system. In order to prepare for a successful pilot of IntelliCare within [redacted], we need to: 1) assess organizational readiness to adopt the remotely delivered mental health service, IntelliCare, and 2) tailor the coaching protocol to fit into the organizational context. We hypothesize that barriers and facilitators to the adoption of IntelliCare will be identified, and that we will learn how to adapt the pre-existing coaching protocol to be acceptable and cost-effective to [redacted] staff and administration. Findings gathered through this preliminary research will be used to inform

future implementation efforts for apps and other behavioral intervention technologies into community settings.

Inclusion and Exclusion Criteria:
[redacted] clinical and administrative staff members (age 18 years and older) who speak English will be eligible to participate in this study. This study will not include special populations such as prisoners, adults unable to consent, and individuals under 18. Any [redacted] staff participating that happen to be pregnant women will not be excluded due to pregnancy.

Study-Wide Number of Participants: N/A-single site

Study-Wide Recruitment Methods: N/A-single site

Multi-Site Research: N/A-single site

Study Timelines:
We estimate that recruiting participants and gathering information from [redacted] staff can be completed with 1-2 visits to their location in [redacted] Timing of the visits will be coordinated with staff availability. We expect focus groups to last approximately 1 hour, and the online survey given to [redacted] staff will take approximately 20-30 minutes to complete. We expect data analyses to take no more than 2 months, and the tailoring of our coaching proctol for [redacted] may take an additional 1 month.

Study Endpoints:
This phase of the project with [redacted] is exploratory and does not have traditional clinical endpoints because subjects are not being randomized. The goal or endpoint in this case will be finalizing an IntelliCare coaching protocol that is tailored to the [redacted] setting.

Procedures Involved:
A REDCap survey will be sent to [redacted] staff members. As seen in the attached copy of the survey, survey items include demographic questions, questions about current work practices, and interest in technology-enabled mental health services, as well as the Implementation Climate Scale, and the Implementation Leadership Scale.

Following the distribution of the survey, research staff from the Center for Behavioral Intervention Technologies will coordinate in-person meetings with [redacted] administration, clinicians, and other staff members, to assess the culture, work attitudes, and morale of the organization. The acceptability of the IntelliCare coach protocol will be assessed through semi-structured interviews and focus groups. See attached for a bank of questions to be asked during these in-person meetings. Semi-structured interviews and focus groups will last between 20-60 minutes, depending on the availability of the participants.
Data will be analyzed using qualitative methods to identify (1) barriers and facilitators to IntelliCare app implementation and (2) methods for tailoring the IntelliCare coaching protocol to fit within [redacted] clinician workflows. This project will provide data to demonstrate the feasibility of a Northwestern-CBITs/[redacted] partnership and produce a coach training manual specific to [redacted]'s needs.

Data and Specimen Banking: N/A

Data and Specimen Management: N/A

Data collected from [redacted] staff will be gathered anonymously through survey responses. During semi-structured interviews and focus group sessions, CBITs researchers will not identify which [redacted] members are providing which pieces of feedback. Therefore, this study will only be collecting data anonymously, with no identifiers for participants, thus meeting IRB exemption status under Category 2.

Provisions to Monitor the Data to Ensure the Safety of Participants: N/A-study involves no more than minimal risk.

Withdrawal of Participants:
Due to data being collected anonymously, there will be no need to identify and withdraw certain participants.

Risks to Participants:
There are no foreseeable risks**,** discomforts, hazards, or inconveniences related to the participants' involvement in the research. This study will consist of an online survey, semi-structured interviews and focus groups, neither of which ask any sensitive or PHI related questions. All participants will have the option to decline to respond to any items on the questionnaire, interview and/or focus groups.

Potential Benefits to Participants:
Participants from [redacted] will receive $5 gift cards for participating in interviews and focus groups and will have the option to enter themselves into a lottery to win one of four $50 gift cards for filling out the survey. The knowledge gained through this process may contribute to benefits for [redacted] staff such as an IntelliCare coaching protocol which could help improve the provision of psychological care within the organization.

Vulnerable Populations: N/A

Community-Based Participatory Research:
This project will involve a community mental health organization in that it will draw from clinicians and staff within this organization and attempt to further knowledge to benefit [redacted] treatment options and processes. Staff members from [redacted] initially reached out to CBITs to establish this partnership, and continuing research with [redacted] will be participatory in nature. Future collaborations between CBITs and [redacted] could help the organization provide a service using the IntelliCare apps to those patients on their waitlist.

Sharing of Results with Participants:
Results of analyses on focus group feedback, interview responses, and survey responses will be presented to administrators, clinicians, and staff at [redacted] in order to inform development of a coaching protocol and further collaboration with Northwestern-CBITs.

Setting:
The study will take place online and then at the [redacted] Central Administration office in [redacted] [redacted] is a community organization providing behavioral health services to >27,000 people annually throughout [redacted] and participants in this study will be staff members involved in the design and delivery of behavioral health services.

Resources Available:

Prior Approvals:
CBITs and [redacted] have been discussing ways to collaborate for several months. Approval from the [redacted] administrative leadership team has been obtained prior to commencing this project.

Recruitment Methods:
All participants will be staff members recruited from the [redacted] organization.
A leader within the organization will be responsible for connecting the PI with potential participants and providing the opportunity for them to contribute to the online questionnaire and to the semi-structured interviews and focus groups.
Staff members will be notified of the opportunity to participate in this research study prior to the research team's site visit by a leader within their organization, and will have the opportunity to discuss their potential involvement in the study with the research team prior to participating in interviews and/or focus groups.

Those who provide feedback in the online questionnaire will have the option to enter themselves into a lottery in which four $50 gift cards will be awarded. The participants who participate in interviews and/or focus groups will be provided with $5 gift cards for their participation.

Number of Local Participants:
This project will include a minimum of 10 and maximum of 600 participants from [redacted] who provide feedback through the online survey and subsequent in-person interviews and focus groups.

Confidentiality: N/A-single site study

Provisions to Protect the Privacy Interests of Participants:
Participation in this project is voluntary and anonymous. All participants have the option to decline to answer any questions from the online questionnaire or the interviews and focus group at any time.

Compensation for Research-Related Injury: N/A-does not involve more than minimal risk.

Economic Burden to Participants:
There are no anticipated economic burdens to participants. Meetings for interviews and focus groups will be scheduled at times convenient to participants, and will not disrupt regular work activities.

Consent Process:

At the beginning of the online survey participants will provide electronic consent.

For the semi-structured interviews and focus groups, the principal investigator, along with other team members from CBITs, will introduce a very brief consent form to all [redacted] staff interested in participating. These consent forms will be handed out to participants during CBITs' in-person visit to [redacted]. Participants will be informed of the in person meeting and opportunities to participate in advance of CBITs' visit. The principal investigator along with other CBITs staff will be present and able to answer questions on the consent while [redacted] review it.
[redacted] participants will be free to decline to participate or refuse to answer questions in the online questionnaire, semi-structured interviews, and focus groups at any time.

For Non-English Speaking Participants: **N/A**

Waiver or Alteration of Consent Process: **N/A**

Participants who are not yet adults (infants, children, teenagers)- **N/A**

***Cognitively Impaired Adults*- N/A**

***Adults Unable to Consent* -N/A**

Process to Document Consent in Writing:
An online consent form will be used for the survey. This consent form will appear at the beginning of the survey and completion of this consent form will allow the participant to proceed to the survey items.

A brief consent form will be presented to [redacted] staff members as a paper document which they can choose to sign/agree to or not during CBITs' visit to their location in [redacted] (see attached document). For those who do not sign the consent form, they will not be included in the interviews, or focus groups nor will they be invited to fill out the online survey.

Drugs or Devices: N/A