A Systems-Level Intervention for Rural Adults with Depression

Study Protocol and Statistical Analysis Plan

NCT04502186

Document most recently approved by University of Michigan's Institution Review Board on April 4, 2023

Specific Aims

The objective of the proposed research is to employ the Replicating Effective Programs (REP) implementation framework and Community-Based Participatory Research (CBPR) principles to develop and test a computer-assisted cognitive behavioral therapy (CBT) for rural persons with depression for group-based delivery in rural church settings, while gathering preliminary information on intervention implementation, including acceptability and feasibility. Almost 20% of Americans meet diagnostic criteria for depression during their lifetime[8] and it is projected to be the second leading cause of disability by 2020.[9] Rural Americans experience depression at rates similar to their urban counterparts,[8,10,11] and the comorbidity of depression and anxiety disorders suggest that as many as 50% of rural residents with depression may also experience anxiety.[12,13] Recent research shows higher mortality rates among rural Americans in midlife compared to urban peers, in part due to higher rates of suicide and substance use. Despite demonstrated need, rural residents are significantly less likely to receive mental health treatment than urban counterparts.[14,15] This unacceptable gap between efficacy research and real world practice in rural areas necessitates the integration of EBPs to usual, preferred care settings. Bridging this gap and increasing rural Americans' access to EBPs for depression requires consideration of availability, accessibility, and acceptability of services. The lack of mental health professionals, transportation challenges, and high costs are substantial barriers to care in rural communities,[16-,26] yet even when treatment is available, many rural persons choose not to seek care. Stigma, shared beliefs and values such as independence and self-reliance, mistrust of formal providers, and explanations of depressive symptoms incongruent with urban-based treatment models, influence rural Americans' attitudes toward help-seeking and have led to a preference for informal systems of care.[19.23,27-34] The proposed research seeks to increase rural populations' access to EBPs for depression by adapting group CBT to be context-specific and for delivery in a non-stigmatizing, accessible setting. As Americans seek help from clergy at high rates,[57-59] and rural Americans report higher levels of religious involvement than urban residents,[60-62] the church setting provides a logical, promising option for delivering EBPs for depression in rural communities. CBT has been shown to effectively treat depression among diverse populations,[36-46] across a variety of treatment settings, and when delivered by lay providers and in their usual care settings.[47-50] Limited research testing CBT in rural communities suggest promising results;[51-55] though all studies include adaptations, yet rarely assess fidelity to standard CBT. These studies suggest the importance of incorporating consumer perceptions of mental illness and treatment and identifying delivery settings that overcome cost and stigma-related obstacles; however, very little attention has been paid to collaborating with rural stakeholders to build interventions for sustainability.[54,56]

The proposed intervention, ***Raising Our Spirits Together (ROST)***, will utilize a community-based participatory approach to adapt and package group CBT for depression for delivery in the rural church setting. ROST will include three components: 1) computer-assisted delivery of core CBT content (e.g., psychoeducation; behavioral activation; cognitive restructuring); 2) multi-media training and manuals for group leaders facilitating sessions (e.g, guide exercises; discuss vignettes and case studies; review homework); and 3) participant workbooks.

Specific Aims of the proposal, guided by the REP implementation framework and CBPR, are:

1) **Intervention Development and Testing.**
    a. Part 1 (see HUM00130956). Utilize a community-based approach to adapt group CBT for depression for the rural context and for delivery in the church setting.
    b. Part 2 (see HUM00173088). Conduct an open pilot test of the adapted intervention. The intervention will be further refined and finalized based on experiences with the open pilot. Adaptation and refinement, guided by perceptions of community stakeholders, provide the best chance at successful integration of an adapted EBP (ROST) into the church setting, maximizing acceptability and sustainability.
    c. Part 3 (focus of current IRB application): Conduct a pilot randomized controlled trial (Phase I/II RCT) of ROST to:
        i. Assess the intervention's preliminary effect on depression among persons living in rural communities
        ii. Explore the relationship between potential mechanisms of change and expected outcomes.

2) **Implementation.** Explore ROST acceptability and feasibility using a mixed method process evaluation to assess multiple stakeholder and partner site perceptions of and experiences with ROST. This will provide insight to implementation facilitators and barriers.

The proposed research has the potential to make a large impact on the lives of individuals living with depression and other mental disorders in rural settings by making CBT available in a preferred community setting and reducing significant barriers related to limited availability of providers, cost, and stigma. Utilizing an established implementation framework, integrated with community-based participatory research principles, to guide intervention adaption and evaluation allows for the development of an intervention with the best chance for acceptability, feasibility, and sustainability in underserved rural communities.

Research Plan

Background

Significance. Depression is a significant public health concern, projected to be the leading cause of disease burden by 2020.[9] Almost 20% of Americans experience depression during their lifetime.[8] When untreated, the disorder has devastating effects on work, family and social life. Despite high prevalence, only one-third of persons with depression seek treatment.[63,64] Rural Americans experience depression at rates similar to urban peers;[8,10,11,65] yet, rural residents are significantly less likely to receive mental health care.[14,15] Despite decades of efficacy research, rural residents are unlikely to receive EBPs for depression.[15,66-69]

Rural residents face substantial barriers to care, the most significant of which may be the shortage of mental health providers. 75% of rural counties lack a practicing psychiatrist[22] and 55% lack a practicing social worker or psychologist.[70] This shortage is exacerbated by access challenges, including high poverty and unemployment rates, high proportions of uninsured or underinsured persons, and travel burden.[16-19,23-26,71]

Even when mental health treatment is available, rural Americans often choose not to seek care. Values of self-reliance and independence contribute to beliefs that psychiatric distress is a weakness, leading to shame and stigma.[27,31-34,72] Lack of anonymity also deters help seeking, as limited social networks make obtaining care without being noticed difficult. Further, rural residents often perceive cultural dissimilarities between themselves and providers.[73] These factors suggest formal mental health services are not acceptable to many rural residents. In fact, rural persons prefer informal systems of care (e.g., clergy, friends, and family).[19,28,35,73-75]

Increasing rural populations' access to and utilization of EBPs for depression requires context-specific adaptations that decrease known barriers. As mental health providers are scarce in rural areas, it is imperative to explore non-mental health settings that could offer treatment. Americans seek help for emotional issues from clergy at high rates.[57-59] Rural residents tend to be more religious than urban residents and churches remain the heart of many rural communities.[60-62] Among a sample of rural southerners with untreated depression, 68% of whites and 93% of people of color stated they would seek mental health services if they were available at church.[19] Offering EBPs for depression at no cost in a non-stigmatizing, accessible church setting is likely to reduce barriers impacting rural populations' treatment utilization. Receiving EBPs from a preferred informal provider in an acceptable setting may increase openness to seeking traditional care if needed in the future. Therefore, the church setting is a promising option for disseminating evidence-based mental health treatment.

Literature suggests church-based interventions for health promotion have potential to reduce disparities; though underscore the importance of utilizing CBPR principles for successful recruitment, participation, and sustainability. Limited work has examined church-based mental health interventions, and only one identified study tested a church-based depression group. Results were promising; however the intervention included a very narrow population (female African American caregivers); did not make adaptations for church setting, did not report collaboration with stakeholders, and did not assess factors related to intervention implementation.

Cognitive behavioral therapy (CBT) is effective for treating depression in group and individual formats,[36-42] among diverse populations,[43-46] across a variety of treatment settings and when delivered by non-mental health professionals in their usual care settings.[47-50] Growing evidence suggests the effectiveness of technology-assisted CBT. Though technology-assisted CBT is helpful for increasing access to care, it has better results when paired with professional support.[77] Therefore, it is likely that clergy, who have strong interpersonal skills, could be trained to facilitate technology-assisted group CBT in church settings. Limited research testing the

effect CBT for depression and anxiety delivered in rural areas suggest promising results;[51-55,78,79] however, all studies include intervention adaptations, yet very few assess fidelity. Further, very little attention has been paid to collaborating with rural stakeholders to build interventions for acceptability and sustainability.[54,56]

The state of knowledge reveals the need for more rigorous effectiveness and implementation research on CBT for depression delivered in rural community settings. The proposed research utilizes the Replicating Effective Programs (REP) implementation framework and CBPR to adapt and pilot test CBT for depression for integration within rural church settings, while exploring acceptability and feasibility. Treating depression often improves anxiety, a secondary outcome. Potential mechanisms of change (Figure 1, below) will be explored.

The proposed intervention, ***Raising Our Spirits Together (ROST)***, will utilize a community-based approach to adapt and package group CBT for depression for the rural context and delivery in the church setting. ROST will include three central components: 1) computer-assisted delivery of core CBT content (behavioral activation; cognitive restructuring); 2) multimedia training and manuals for group leaders; and 3) participant workbooks. This format is consistent with self-help programming commonly offered in churches (e.g., Purpose-driven Life[80]; 40 million copies sold), but distinct due to its use of EBP. Given the existing infrastructure for delivering small group programs, the church setting is well suited for deploying group CBT.

Research Strategy

The primary aim of this research is to develop and test a computer-assisted group-based cognitive behavioral therapy for depression, entitled Raising Our Spirits Together (ROST), that will be delivered within church settings in rural Hillsdale County, Michigan. The primary aim is comprised of three distinct phases, which are described in detail below:

Part 1: Intervention Development. This aspect of the project is associated with a separate IRB application: HUM00130956.

Part 2: Open Pilot of ROST. This aspect of the project is associated with a separate IRB application: HUM00173088.

Part 3: Randomized Controlled Trial (Phase I/II RCT) of ROST compared to and Enhanced Control Condition. This aspect of the project is the focus of the current IRB application and the following protocol is specific to the Phase I/II RCT.

The secondary aim of this research is to gather preliminary information on ROST implementation.

Aim 1: Develop and test a computer-assisted group-based cognitive behavioral therapy (CBT) for depression (Raising Our Spirits Together (ROST))

Part 3: Randomized Controlled Trial (Phase I/II RCT) of ROST compared to and Enhanced Control Condition

Purpose. The purpose of this project is to conduct a Phase I/II RCT of ROST, evaluating its preliminary effect on depression relative to an enhanced control condition (ECC; see below).

Intervention Arm: Raising Our Spirits Together (ROST). ROST is an 8-session, computer-assisted, group-based cognitive behavioral therapy (CBT) for depression that is intentionally designed for delivery by clergy in rural church settings or remotely via secure videoconference software available via the University of Michigan. ROST uses a combination of video-based educational content, text-based educational content, and a character-driven storyline to introduce core CBT concepts, including psychoeducation, behavioral activation, cognitive restructuring, and problem solving. The ROST intervention package also includes a participant workbook and intervention manual for group leaders.

Session by Session Overview

Session 1 – Psychoeducation and Introduction
Session 2 – Behavioral Activation
Session 3 – Behavioral Activation
Session 4 – Cognitive Restructuring
Session 5 – Cognitive Restructuring
Session 6 – Faulty Beliefs
Session 7 – Problem Solving/Overcoming Setbacks
Session 8 – Program Overview and Relapse Prevention

ROST was intentionally designed to deliver CBT in a way that is robust, yet widely accessible. Therefore, we paid close attention to the reading level of our content, used a combination of text, audio, and graphics to introduce core concepts in order address multiple learning needs, and streamlined interactive exercises and homework/action plan exercises to be more intuitive and less cumbersome/academically-oriented while focusing on the same central concepts. Our community-engaged intervention development work led to the selection and integration of images, quotes, vignettes, and examples that are likely to be most relevant and relatable for this setting. For example, each session begins with a quote from scripture that connects to the core CBT content being taught that day. We also identify potential activities for behavioral activation in Session 2 and 3 that can be done for free and within the rural context that lacks resources and infrastructure. Additionally, aspects of rural culture, related to self-reliance and independence, led to the inclusion of "I cannot ask for help" as an example of a faulty belief we explore in Session 6. Another central adaptation related to our use of character driven content that compliments and reinforces core CBT session content. The character-driven, video-based content was designed to enhance participant engagement in ROST. The character also shows how she used CBT in her life, which provides a concrete example to participants as they apply CBT concepts in their own lives.

Please note that documents presenting comprehensive content for every ROST session are provided as part of the IRB application. Images of the computer-assisted platform and character-driven content have been submitted as supplemental materials in the IRB application as well.

Participants randomized to ROST will complete weekly sessions that last for approximately ninety minutes (8 sessions total). ROST will either be delivered in-person at one of our partner churches, or virtually, via secure, web-based videoconferencing software available through the University of Michigan. The pastor will facilitate in-person and virtual pilot groups. Participants randomized to ROST will receive $10 for each ROST session they attend to compensate them for travel and parking expenses.

Clinical Backup. We recognize ROST leaders will need clinical backup. Dr. Himle and Ms. Tucker, who are both licensed clinical social workers, will provide clinical backup and will be available for group leaders via phone or video conference consultation if a study participant's condition worsens or suicidality is present. Contact between clinical backup, group leaders, and study participants will be tracked to inform ROST feasibility. Study team members providing clinical back up will complete a half-day training that includes an overview of ROST, their role, and relevant study procedures related to risk assessment and safety planning.

Control Arm: Enhanced Control Condition (ECC). An enhanced control condition (ECC) is an appropriate comparison condition for the RCT, given the limited treatment access in the rural target community. When participants screen positive for depression, there is an ethical obligation to provide resources and referrals. ECC participants will receive a self-help workbook that provides psychoeducation,[109] as well as local resource guides and appropriate referrals. Ongoing risk assessment of ECC participants will occur at post-treatment (PT) and follow-up (FU) assessment timepoints. The suicide risk protocol (see Protection of Human Participants) will be followed if suicidal ideation is present.

Participants and Recruitment.

Enrollment and Participants. We expect to recruit and enroll 128 men and women *who live within Hillsdale, Lenawee, Calhoun, Jackson or Branch County, Michigan* to participate in this Phase I/II RCT of ROST.

Hillsdale, Lenawee, Calhoun, Jackson and Branch counties are all rural counties within Michigan that are a designated mental health provider shortage areas. The poverty and unemployment rates in these three counties are above the national average. We expect to screen 177 persons, with 80% meeting screening criteria, providing informed consent, and agreeing to BL interviews (N=160). Of those 160 participants, we expect 80% who complete BL interviews will meet eligibility criteria (N=128). We expect 80% of those 128 participants to attend randomization (N=103). Of those attending randomization, we expect 82% (N=84; ROST=42; ECC=42) to participate in their assigned condition and be included in the RCT (Power analysis described below).

Recruitment. Community-based recruitment, via both in-person and virtual/web-based strategies will be used. These strategies will include putting up flyers in community locations (e.g., libraries, coffee shops, grocery stores, restaurants, schools, churches, social service agencies), airing an ad on the local radio station, and posting recruitment materials on relevant community websites and social media sites. We will put study flyers up at our church study sites and the pastors may directly refer potential participants to the research project. Study team contact information will be on all recruitment materials. Interested potential participants may contact us directly. If potential participants are referred to the project by a social service provider or clergy and are interested in participating, they will have the option to complete a contact form so a research associate from the study team can contact them at a later time. The contact form will ask participants to provide a phone number, additional contact persons, and an email address, and to identify their preferred method of contact. Confidentiality is emphasized.

In-person research will follow many safety protocols due to COVID-19. In-person recruitment will only be outdoors. Before beginning conversation with participants, an abbreviated health screen will be administered. Specifically, interested individuals will be asked whether, in the past 24 hours, they have had: 1) a fever, 2) a cough, 3) nasal congestion, 4) loss of taste/smell, 5) close contact with anyone who tested positive for COVID-19 or is positive for COVID-19. If any interested individual endorses two or more symptoms, study team members will not engage with them at that time. They will be provided with recruitment materials and can reach out by phone or email at a later time.

Plans for social distancing include conducting recruitment activities outdoors only. At these outdoor settings (e.g., food bank, farmers market), a study team member will set up a booth that allows for at least six feet of distance between staff and individuals interested in learning about the study. Staff will bring signage to communicate expectations for social distancing (i.e., keeping at least 6 feet apart) as well as signage that can be placed on the ground in front of the booth to provide a visual of 6 feet distance necessary to maintain between individuals.

Staff will complete the ResponiBlue screening daily and wear masks when engaged in outdoor recruitment. Individuals interested in the study will be encouraged to wear masks and extra masks will be available to interested individuals who approach the booth without a mask. Hand sanitizer and cleaning wipes will be kept at the booth at all times. Staff will wipe down the booth and use hand sanitizer after interacting with each individual interested in the study. Single use pens will be available at the booth for interested individuals to use. Interested individuals can complete a contact form with their contact information so that a study team member can reach out to them about the study. Contact forms can be dropped into a plastic box. The contact forms will be removed from the box at the end of the day and put into an envelope. The box will be sanitized with cleaning wipes.

Research associates will contact potential participants who voluntarily complete a contact form by phone or email and briefly describe the study. If the potential participant remains interested, the research associate will schedule a phone screen to determine initial eligibility.

All recruitment materials for the open pilot will avoid stigmatizing terms and include diverse images in terms of race/ethnicity, gender, and age, promoting inclusiveness.

Inclusion. In order to participate in this study, persons must: 1) currently live in Hillsdale, Branch, Jackson, Calhoun, or Lenawee County, Michigan. All persons residing in these counties may participate, regardless of religious beliefs; however, like Alcoholics Anonymous, participants will be informed of and must accept that non-denominational Christian-based quotes and images are included; 2) screen positive for at least mild depressive symptoms on the Patient Health Questionnaire-9 (PHQ-9>=5); and 3) not currently receive Cognitive Behavioral Therapy (CBT) treatment. Persons taking medication for depression may participate. Medication use will be monitored. Participants will be advised to continue taking any psychiatric medication according to their clinician/physician's instructions; though medication stabilization will not be required for inclusion. Dr. Himle's research in non-mental health settings suggest medication stabilization is not feasible given the likelihood of multiple prescribing providers. Depressive disorder diagnoses will be assessed via structured interview (MINI v 7), but is not required for inclusion. Depressive disorder diagnosis will be considered in analyses. This increases access for underserved persons with a range of symptoms; helps fill groups faster; and is most generalizable to real world implementation.

Exclusion. Persons will not be eligible for the study if they 1) are non-English speaking; 2) currently receive regular CBT for depression (>1 time per month); 3) ever completed a course of CBT (>=8 sessions); 4) have a psychotic disorder; 5) currently use opiates cocaine; 6) have cognitive impairment (>=2 incorrect items on the 6-item mini mental status exam); or 7) have prominent suicidal/homicidal ideation with imminent risk. Indicators for imminent risk will be assessed by the interviewer. Subjects with significant suicide/self-harm or homicide risk must be excluded on ethical grounds and will receive appropriate resources and referrals (see Protection of Human Participants).

Randomization. Persons meeting eligibility criteria will be randomized to ROST or the ECC. Randomization will occur in replicated blocks across conditions. This procedure will repeat until 7, six-member ROST groups and 7, six-member ECC groups are assembled. If participant flow prevents timely assembly, smaller groups will be considered to avoid extended delays.

STUDY SITES: There will be two study sites for the RCT, located in Hillsdale County. The study sites are our partner churches, Trinity Lutheran Church and Jonesville First Presbyterian Church. ROST will either be delivered in-person at one of our partner churches, or virtually, via secure, web-based videoconferencing software available through the University of Michigan. The pastors will facilitate in-person and virtual ROST groups.

PROCEDURES.

Screening. Individuals interested in participating in this study will either contact the study team independently or will complete a contact form permitting University of Michigan to contact them. Research Associates will communicate with interested participants via phone and will privately explain the purpose of the study. If potential participants are still interested in the study, Research Associates will invite them to complete an initial phone screening. Research Associates will obtain oral consent from potential participants before beginning the initial phone screening.

Potential participants who provide oral consent will complete an initial screening over the phone with a trained Research Associate. The phone screening will take about 8-10 minutes and will assess the initial inclusion criteria. The phone screen will include a depression screen (PHQ-2) administered by a trained Research Associate. Potential participants will also be asked screening questions regarding age, how long they have resided in Hillsdale, Lenawee, Jackson, Calhoun or Branch County, MI and their psychosocial treatment history. All persons who meet initial eligibility criteria, including scoring >=2 on the PHQ-2, will be invited to participate in a baseline interview to determine further eligibility. If potential participants are interested in moving forward with study participation, the RA will work with the potential participant to schedule a baseline interview at their convenience. Potential participants will not be remunerated for the screening phase of the study. Reasons for screening and baseline refusal will be collected and coded for use in data analysis.

Consent. Before completing the baseline interview, Research Associates (RAs) will obtain informed consent from all participants. The Research Associate will schedule a meeting with potential participants, either in

person or virtually, via secure, web-based videoconferencing software available through the University of Michigan (i.e., Zoom) to review the informed consent document and answer any questions potential participants have about the study. If potential participants would like to participate, they will provide informed consent. If RAs and potential participants meet in person, written, informed consent will be obtained. The participant and the RA will each keep a copy of the document for their records. If RAs and potential participants meet virtually, RAs will send the potential participant a REDCap survey link that includes the informed consent document. After reviewing the consent document, potential participants who would like to participant will electronically sign the document in REDCap. The RA will send also participants a copy of the consent document via email.

Assessment Interviews. All RCT participants (ROST and ECC) are to complete baseline, post-treatment (PT) and 3-month follow-up (FU) interviews (see Table 4., below). At FU, participants randomized to ROST also complete a qualitative interview focused on their perceptions of treatment. Supplemental questions will be included for participants who did not respond to ROST and those who dropped out of treatment to gather information on intervention acceptability, feasibility, and choice points. RCT participants will receive $25 for each assessment interview completed. Each assessment interview will take approximately 2 hours. Participants randomized to ROST will also receive $20 for completing the qualitative interview at the FU time point.

Baseline Interview. All participants who meet screening eligibility criteria and consent to participant in the research study, will complete a baseline interview to diagnose depression and comorbid psychiatric conditions and assess other psychometric and demographic variables (see Table 4). This interview will take approximately 2 hours to complete. The interview will be completed in person or over the phone or secure, web-based videoconferencing software available through the University of Michigan (i.e., Zoom). Participants will receive $25 for completing the baseline interview. All baseline interviews will be completed by clinical interviewers that have clinical mental health experience and education and have received extensive training in interview-based measures.

In-Session Measures. Participants randomized to ROST will complete a series of measures after each ROST sessions. The measures will be completed via REDCap online survey software. If ROST is held in person, participants will complete the online measures on site via a tablet. If ROST is held virtually, RAs will administer the online measures using REDCap online survey software distributed via email for the participants to complete after the group, while still in the Zoom room with RAs. Participants will complete weekly depression ratings (PHQ-9) to track symptoms during ROST. If participants endorse suicidal ideation on the PHQ-9 (score >0 on Question 9), they will complete the Columbia-Suicide Severity Rating Scale (C-SSRS). C-SSRS scores will be calculated via the REDCap survey software and connected to the corresponding suicide risk level (established via C-SSRS). If measures are completed onsite via table, all participants who complete the C-SSRS will be prompted by the online survey software to check in with their group leader and a Research Associate who will review their scores and risk level. If measures are completed by phone with an RA, the RAs will receive the participant's C-SSRS score and the risk level in real time. If a participant is at low risk, the Research Associate will encourage them to call the local Psychiatric Emergency Service and to discuss feelings with family members. Participants who are at low risk for suicidal ideation will continue participating in ROST sessions and their suicidal ideation will be monitored weekly until it is minimal. If a participant is at moderate or high risk for suicidal ideation, the Research Associate will immediately connect them to clinical back up – either Dr. Himle or Ms. Tucker – both of whom are licensed clinical social workers. The clinical back up will assess risk and develop a safety plan with the participant and the Research Associate. After the plan is developed, it will be documented by the Research Associate who will complete a text-entry action plan via the REDCap survey. Please see the Human Subjects Protection section for a detailed description of risk levels and associated action/safety plans. Participants randomized to ROST who experience clinical deterioration over time in treatment (as indicated by an increase of 5 points or more on the PHQ-9 for participants with scores of 10 or above) will be contacted by a study team member and referred to local resources that can provide an increased level of care. Participants will also complete the Automatic Thoughts Questionnaire and the Behavioral Activation for Depression Scale at each weekly ROST session. The Group Cohesion Scale will be completed during Sessions 1, 4, and 8 and the Expectancy Rating scale will be completed during Session 3.

Follow-up interviews. All participants who completed the baseline mental health assessment interview will complete interviews at post-treatment (PT) and at 3-month follow-up (FU) timepoints. These interviews will be completed in person, over the phone, or via secure, web-based videoconferencing software available via the University of Michigan (i.e., Zoom). Research Associates will administer the same measures at post-treatment and 3 month follow-up that were assessed during the baseline interview (see Table 4). Supplemental questions will be asked to participants randomized to ROST who did not respond to the treatment or dropped out of treatment. This will allow us to gather information on intervention acceptability, feasibility, and choice points. Participants will receive $25 for completing follow up interviews. These interviews will take about 1.5 hours to 2 hours.

Treatment Fidelity and Group Leader Competence. To ensure fidelity, an independent assessor (IA: Masters-level clinician with CBT experience and study-specific training) will rate leader adherence and competence using a version of the Collaborative Study Psychotherapy Rating Scale-Cognitive Therapy[105] and the Cognitive Therapy Scale[106] adapted for this study. All RCT sessions will be audio-recorded with participant consent and rated by the IA for treatment adherence and leader competence. Dr. Himle and Dr. Weaver will review audio-recordings and competency ratings. The IA will regularly attend research meetings to discuss findings. Dr. Himle and Dr. Weaver will provide weekly supervision to group leaders. Dr. Weaver and Dr. Himle will review recordings for coverage of content and group leader competence, addressing any issues during weekly supervision with group leaders. We will develop a plan to incorporate missing content into the next session.

Maintenance of samples*.* Strategies will be used to encourage attendance of group sessions and to complete follow up interviews. Reminder emails, calls and/or text messages, based on participant preference, will be sent the day before each group session to remind participants of the group meeting times or interview times. If a participant misses a session, they will be contacted by the group leader and/or the research associate. The study team will stress the importance of attendance for the group sessions. The study team will collect participant addresses, phone numbers and email addresses as part of the baseline assessment. This contact information will be updated regularly by the study team throughout the study period. Participants will also be asked to identify contact persons that do not live with the participant and will know the participants whereabouts, if the study team cannot reach the participant. Participants will also receive compensation for completing interviews and group sessions.

ROST retention. All participants randomized to ROST will receive a schedule of the dates and times for all 8 ROST sessions prior to (if group is virtual) or at Session 1 (if group is in-person). During session one, group leaders will emphasize the importance of attendance. If a participant misses a session, the group leader or a research associate will call the participant to discuss the reason for missing the session and to discuss potential barriers to attending future sessions. Additional contact information, described in Maintenance of Samples, above) will be collected at baseline and used to reach participants if group leaders cannot contact a participant using primary contact information.

Assessment retention. Participants will be assessed at post treatment and 3-month follow up time points. Participants will be asked to schedule their 3-month follow up interview at their post treatment interview. If the PT interview is in-person, the Research Associate will give participants a business card that includes their FU interview date and time, along with the location of the interview, and payment information. If the PT interview is virtual, the Research Associate will email the participant their FU interview date and time, along with the location/zoom link for the interview, and payment information. An online calendar invite will be sent to participants as well. *To retain participants during the follow up period, participants will be sent bi-weekly check-ins via mail, email, phone, or text (based on participant preference) to ensure that their contact information is up to date, and to remind them of their next interview*. Participants will be given the option to complete an interview at their home or virtually, if there are travel barriers.

Group leaders and training. The group leaders will complete training program developed by the study team. First, group leaders will complete a web-based training on CBT for Depression created by Dr. Ken Koback.

Next, the trainees will complete one full day of in-person training with Dr. Weaver and Dr. Himle. This in-person training will include didactic modules on depression, cognitive behavioral therapy for depression, group facilitation skills and safety planning. After completing the didactic modules, the group leaders will complete a second day of in-person training focused on the ROST intervention. The training will include a review of the computer-assisted program, the group leader manual, and fidelity ratings. The group leaders will be asked to role play the core components of the intervention (cognitive restructuring, behavioral activation, relapse prevention) as well as key group leader roles/responsibilities, including introducing workbook exercises, leading weekly check-ins, and reviewing homework. At the end of the second day of in-person training, the group leader will complete the Cognitive Behavioral Therapy Knowledge Questionnaire. Gaps in knowledge will be addressed as needed by the study team. Throughout the RCT, the group leaders will receive ongoing supervision and training. All ROST sessions will be audio recorded. The audio recordings will be reviewed by both Dr. Himle and Dr. Weaver. Weekly supervision will be held with Dr. Weaver, Dr. Himle, and the group leader to review session audio tapes and address additional training needs.

MEASURES (see Table 4 for administration schedule).

Depression Screening. Individuals interested in participating in the study will complete an initial phone screening that will include the PHQ-2. The PHQ-2 is a two-question measure that screens for depression. If an individual receives a score of 2 or higher on the PHQ-2 they will be asked to schedule a baseline interview to further determine eligibility.

Screening for Cognitive Impairment. Individuals interested in participating in the study will complete an initial phone screening that will include the 6-item Mini Mental Status Exam. The 6-item Mini Mental Status Exam screens for cognitive impairment and dementia. If an individual gets a score of 4 or higher on the Mini Mental Health Status Exam they will be asked to schedule a baseline interview to further determine eligibility.

Diagnostic interviews. Diagnostic interviews assessing DSM-V disorders at baseline, post interview and 3-month follow up interviews will be conducted using the Mini International Neuropsychiatric Interview v.7(MINI; Sheehan et al., 2015). The MINI will be administered by Research Associates blinded to treatment conditions. The MINI is a widely used structured interview with excellent test-retest and interrater reliability. All Research Associates who conduct diagnostic interviews are trained to a standard (see Diagnostic interviewer training & inter-rater reliability, on page 7.

Measures of subjects' depressive symptoms. The primary outcome measure for assessing ROST's preliminary effect on depression is the PHQ-9. The PHQ-9 is a nine item measure that assesses depression severity as a continuous measure. Further, the PHQ is a widely-used instrument found to adequately measure depression outcomes in response to depression treatment. Depressive symptoms will also be assessed via the Beck Depression Inventory (BDI). The BDI is a widely-used 21-item scale that assesses depression severity.

Measures of client functioning. Overall disability will be measured using Sheehan Disability Scale (SDS; Sheehan, 1996). The SDS is a commonly used three-item measure of functional impairment. In addition, we will measure quality of life using the Quality of Life and Enjoyment Questionnaire (Q-LES-SF). This is a 14-item scale that will be administered at each time point.

Measures of other symptoms in subjects. We plan to assess comorbid anxiety symptoms using Generalized Anxiety Disorder Scale, GAD-7. The GAD-7 is a widely used measure with well-established reliability and validity.

Measure of group cohesion. We will administer the Group Cohesiveness Scale (GCS; ref), a 7-item self-report questionnaire assessing perceptions of group cohesiveness, during Sessions 1, 4, and 8. The scale has satisfactory psychometric properties (ref).

Demographics. Collected demographic information will include gender, date of birth, race/ethnicity, education level, family composition, employment status, and other relevant clinical and demographic characteristics.

Measures of treatment credibility and beliefs. Treatment expectations will be measured using the Expectancy Rating Scale (Borkovec & Nau, 1972). This is a four item self-report instrument designed to assess patient expectations regarding change with treatment. The Expectancy Rating Scale will be administered during the baseline interview and again during Session 3 of the ROST intervention so that participants can report expectations after they have been well socialized to the treatment. The Expectancy Rating Scale has high internal consistency and high test-retest reliability (Devilly et al., 2000). Treatment satisfaction will be rated using the Treatment Impressions Rating Scale, a Likert-based self-report instrument.

Perceived stigma of mental illness. Participants' perceptions on mental illness stigma will be measured using Perceived Devaluation and Discrimination Scale[98] (PDDS; public stigma). This is a 12-item scale that participants will complete at each time point. We will also be using the Internalized Stigma of Mental Illness Scale, which will measure internal stigma. This is a 29-item scale that participants will complete at each time point.

Measures of Thoughts. Participants' thoughts will be measured using the Automatic Thoughts Questionnaire and the Dysfunctional Attitudes Scale – Short Form. The 30-item Automatic Thoughts Questionnaire (ATQ) will be completed by participants at every ROST session and has adequate validity and reliability. The 18-item Dysfunctional Attitudes Scale – Short Form will be completed by participants at the baseline, post-treatment, and 3-month follow up assessments. The Dysfunctional Attitudes Scale – Short Form has adequate psychometric properties.

Measures of Behaviors. Participants' behaviors will be measured vis the Behavioral Activation for Depression Scale (BADS) and the Environmental Reward Observation Scale (EROS). BADS is a 25-item measure that will be completed by participants at every ROST session. The EROS is a 10-item measure that will be completed by participants at all three assessment timepoints.

Measure of Social Support. Social support will be measured using the Interpersonal Support Evaluation List - 12 (ISEL-12). This 12-item measure will be completed by participants at baseline, post-treatment, and 3-month follow-up. The ISEL-12 has adequate psychometric properties.

Measure of Willingness to Accept Help. Participants' willingness to accept help will be assessed using the 10-item Attitudes Toward Seeking Professional Psychological Help Scale – Short Form and the 24-item Perceived Barriers to Psychological Treatment. Both measures will be completed at baseline, post-treatment, and 3-month follow-up time points.

Measure of Religiosity. The 5-item Duke University Religion Index will be used to assess religiosity at baseline.

Measure of User Engagement. The 12-item User Engagement Scale-Short Form will be used to assess users' level of engagement with the computer-assisted Raising Our Spirits Together intervention at the post-treatment assessment.

Measure of Service Use. Participants' use of mental health treatment and services will be assessed at the 3-month follow up assessment. Treatment and service use will be assessed using the Follow-up Mental Health Service/Medication Use Questionnaire.

Table 4. Measure Administration Schedule

Table 4. Measure Administration Schedule				
Category	**Measures**	**Items**	**Timepoint(s)**	**Type**
Screening	Patient Health Questionnaire-2 (PHQ-2)	2	Screening	PR

	6-item Mini Mental Status Exam	6	Screening	IA
Diagnosis & Symptom Scales	Patient Health Questionnaire-9[81] (PHQ-9)	10	BL PT FU; Sessions 1-10	PR
	MINI International Neuropsychiatric Interview v. 7 for DSM-V disorders[89] (MINI)	60 +	BL, PT, FU	DI
Symptom Scales	Beck Depression Inventory[90] (BDI)	21	BL. PT, FU	PR
	Generalized Anxiety D-7[91](GAD-7)	7	BL, PT, FU	PR
Functional Impairment	Sheehan Disability Scale[92] (SDS)	3	BL, PT, FU	PR
	Quality of Life Enjoyment & Satisfaction Questionnaire – SF[93] (Q-LES-SF)	14	BL, PT, FU	PR
Mechanisms of Change	***Thoughts***			
	Automatic Thoughts Questionnaire[94] (ATQ)	30	Sessions 1-10	PR
	Dysfunctional Attitudes Scale – Short Forms[95] (DAS)	18	BL; PT; FU	PR
	Behaviors			
	Behavioral Activation for Depression Scale[96] (BADS)	25	Sessions 1-10	PR
	Environmental Reward Observation Scale[97] (EROS)	10	BL; PT; FU	PR
	Stigma			
	Perceived Devaluation and Discrimination Scale[98] (PDDS; public stigma)	12	BL, PT, FU	PR
	Internalized Stigma of Mental Illness Scale[99] (ISMIS; internal stigma)	29	BL, PT, FU	PR
	Social Support			
	Interpersonal Support Evaluation List -12 (ISEL-12)[100]	12	BL, PT, FU	PR
	Willingness to Accept Help			
	Attitudes Toward Seeking Professional Psychological Help Scale - SF[101]	10	BL, PT, FU	PR
	Perceived Barriers to Psychological Treatment[102]	24	BL, PT, FU	PR
Moderators	***Religiosity***			
	The Duke University Religion Index[103]	5	BL	PR
	Depression Severity			
	Beck Depression Inventory[90] (BDI)	21	BL	PR
	User Engagement			
	User Engagement Scale -Short Form	12	PT	PR
Service Use	Follow-up Mental Health Service/Medication Use Questionnaire[104]		FU	PR
Treatment Fidelity & Adherence	Collaborative Study Psychotherapy Rating Scale – Cognitive Therapy[105]	28	Sessions 1-10	IA
	Cognitive Therapy Scale[106]	13	Sessions 1-10	IA
	Expectancy Rating[107]	6	BL, Session 3	PR
	Group Cohesiveness Scale[108]	7	Sessions 1,5,10	PR
Abbreviations: PR: Participant Report; DI: Diagnostic Interview; IA: Independent Assessor				

Diagnostic interviewer training & inter-rater reliability. Diagnostic interviewers with clinical experience and and graduate-level mental health training will be trained to complete interviews (MINI v. 7). They will be trained by Dr. Weaver and Ms. Tucker via a didactic training course. Trainees will be asked to rate gold standard interviews until they are able to achieve agreement on diagnostic ratings for three consecutive interviews.

Then, each clinical interviewer will be asked to conduct a role play of two diagnostic interviews. The clinical interviewer will be observed doing three or more interviews until there is a 90% agreement on the MINI. Audio tapes of diagnostic interviews will be reviewed by Dr. Weaver and Ms. Tucker and weekly supervisions will be held with clinical interviewers to review tapes, review diagnosis, and address additional training needs.

***Data Analyses*.** Primary outcome measures for assessing ROST's preliminary effect on depression relative to ECC are the PHQ-9 and BDI. We expect to enroll 128 subjects, 84 of whom we anticipate will participate in the study after randomization to condition. A sample of 84 subjects who participate in their study condition after randomization should provide power of .8 to find a significant (at 2-tailed $p < .05$) comparative effect size for intervention change of d=.8 or above, which is in ranges found in CBT meta-analyses.[110] Analyses will adjust for BL scores to increase precision and maximize power. Other BL covariates will be examined for association with outcome variables. Those accounting for change in the estimated treatment effect will be retained in final analyses to optimize power and precision.[111] As ROST is group-based, with participants blocked on time of screening prior to randomization, individuals' observations cannot be assumed independent. Due to lack of independence, mixed linear (multilevel) growth modeling[112] will be used to test for the preliminary effect of ROST relative to ECC on outcome variables. Mechanisms of change will be explored by adding change on variables targeted by the intervention (thoughts; stigma) as time-varying covariates to multilevel models predicting change in depression over time.[113] To explore the possibility that treatment effects may differ for those presenting with low v high religiosity and moderate v severe depression, baseline religiosity and baseline depression severity will be examined as potential moderators. Although this RCT is not powered for mediation or moderation tests, effect sizes from these analyses will inform future fully powered research to test mechanisms of change. Analyses will be "intent-to-treat," as all subjects undergoing randomization will be included, and will use multiple imputation methods[114] and pattern mixture modeling[115] to handle data missing at follow-up and sensitivity analyses to examine the influence of missingness on findings.

PROTECTION OF HUMAN PARTICIPANT(S)

This project meets the definition of a clinical trial. This section describes the Protection of Human Participants.

HUMAN PARTICIPANTS INVOLVEMENT AND CHARACTERISTICS

All study procedures will be approved by the University of Michigan Medical School's Institutional Review Board prior to implementation. The proposed study will involve recruiting persons age 18 and above living in Hillsdale, Lenawee, Jackson, Calhoun or Branch County, Michigan, and screening interested persons located in the target communities. Informed consent will be procured following the screening. All subjects will be told that participation is voluntary and can be withdrawn at any time. Participants will also be advised that information provided will be kept confidential. Limits to confidentiality (i.e. prominent suicidal or homicidal ideation with imminent risk, child abuse) will also be discussed and provided in written format. Included persons will be aged 18 and older, residents of the target community for at least 12 months, with at least mild depressive symptoms (PHQ-9 >= 5), who are not currently receiving psychosocial treatment. Persons will not be eligible for the study if they are (1) non-English speaking; (2) currently receiving regular psychotherapy for depression: (3) have ever completed a prior full course of CBT (>=8 sessions); (4) meet criteria for any psychotic disorder; (5) current use of opiates or freebase cocaine; (6) have cognitive impairment (>=2 incorrect items on the 6-item mini mental status exam); or (7) present with prominent suicidal/homicidal ideation with imminent risk. Persons will be screened for the presence of elevated depressive symptoms that are currently untreated, including suicide risk. Any participant determined to be at imminent risk for suicide will be referred to the psychiatric emergency services at the Dempster W. Muffitt Center for Psychiatric Care at the Hillsdale Community Health Center. If they refuse a referral, standard clinical safety protocol will be followed (see below).

Gender and Minority Inclusion. Participants will be recruited from Hillsdale, Lenawee, Jackson, Calhoun, or Branch County, Michigan through advertisements and referrals from local clergy and mental health, primary care, and human service providers. Given epidemiologic data on depression prevalence, it is expected that our sample will be 67% women and 33% men. Census data for Hillsdale county suggests the community is 97% white; 2% Hispanic, and 1% African American. Special attention will be made to recruiting minorities through

targeting churches with sizable Hispanic and African American congregations. Therefore, we expect to recruit approximately 90% White participants; 5% Hispanic participants; and 5% African American participants.

Removing Participants from the Protocol. Based on our experience, removal of participants from the protocol for clinical reasons is expected to be very rare, and established procedures are available to appropriately respond to various forms of clinical deterioration. Participants may be removed from the trial for the reasons listed below. In each case, participants will be consulted regarding potential removal. Final judgment for participant withdrawal will be made via consensus of group leaders, PI: Addie Weaver, and Co-I: Joseph Himle. Effort will be made to continue assessment of any participants removed from the trial. Withdrawn participants will be referred for the best available treatment outside the research protocol.

Clinical Deterioration. During the active intervention phase, participants who experience clinical deterioration over time in treatment will be evaluated and removed from the trial. Clinical deterioration is defined as significant worsening of depressive symptoms, based on a 5 point increase on the PHQ-9 for those with scores of 10 and above. These participants will be contacted by a study team member and referred to local resources that can provide an increased level of care. Worsening suicidality or comorbid conditions that are determined to compromise participant safety will also be grounds for participant removal. These concerns may come to our attention directly via the group leaders, participants, or family members. Additionally, participants who endorse any level of suicidal ideation on the PHQ-9 (>0 on question 9) will complete the Columbia Suicide Severity Rating Scale (C-SSRS). Participants whose scores indicate low risk for suicidal ideation on the C-SSRS will continue participating in the intervention and their suicidal ideation will be monitored weekly during that time. Participants whose scores indicate moderate or high risk for suicidal ideation on the C-SRSS will be connected to clinical back-up, connected to appropriate resources, and monitored. A safety-monitoring plan will be in place for participants experiencing worsening severity during the waiting period prior to treatment assignment or during the follow-up period.

In addition, at first contact, participants will be provided with an information sheet detailing procedures for contacting investigators should their depressive symptoms, comorbid symptoms, or risk for harm to self or others become a source of concern. If any of the scheduled reassessments reveal worsening depressive symptoms, comorbid symptoms, or risk for harm to self or others, a repeat face-to-face assessment will be completed, including the PHQ-9, CSRSS, BDI, and MINI. If there is a clinically significant worsening on the PHQ-9 or CSRSS relative to the prior assessment, significant effort will be made to expedite entry into the best available treatment outside the research protocol.

*Treatment Non-Participation***.** If a participant does not participate in a session they will be counseled by one of the group leaders and a plan will be put in place to encourage participation. If a participant misses three consecutive sessions and the group leader cannot reach them, the group leader will stop reaching out. Study team members will still reach out to invite the participant to complete follow up assessments and document their reasons for discontinuing treatment.

Interference with group process. If a participant interferes with the group process due to extremely disruptive behavior, the participant will be counseled to minimize interference. If the disruptive behavior persists, they will be removed from ROST treatment.

SOURCES OF MATERIAL

Data will be collected only with written informed consent from the participant. Two sources of data will exist for this study. First, participants will respond to structured assessments created to gather screening, baseline, and follow-up data. The majority of proposed instruments have been widely used. Second, digital recordings of semi-structured qualitative interviews focused on intervention group participants' perceptions of the intervention, audio recordings of the focus groups conducted after each open pilot session, and audio recordings of all open pilot and RCT sessions will be collected to ensure treatment integrity. Such recordings will only be gathered with informed consent. All of the information will be collected specifically for this research project. Participant identifying information (i.e. name, address, telephone number) will be kept separate from

their responses. Identification codes will be assigned to participants. These codes will also be kept separate from identifying information except for the purpose of follow-up interviews. These connections will be destroyed once the data is collected.

Data, coded only with unique identifying code numbers, will be stored separately of identifying information. All data will be stored in locked files, accessible only to the Principal Investigator and key study personnel. All data collected via paper measures will be scanned and stored on password protected computers on the University of Michigan's secure server. REDCapwill be used to electronically collect data at each session during active groups. University of Michigan has a license with REDCap and the program is HIPAA compliant. Data collected electronically will be exported from REDCap and stored on password protected computers on the University of Michigan's secure server. All published reports will contain data reported either in aggregate form (where no individual responses can be identified) or in composite individual examples that are constructed so that identification is not possible. In addition, all levels of staff will have completed the University of Michigan's web-based Program for Education and Evaluation in Responsible Research and Scholarship (PEERRS).

POTENTIAL RISKS

Participants are revealing personal information about themselves in this study, through structured assessments and through audio recorded qualitative interviews, focus groups, and intervention group sessions. Thus, the primary risk to participants in this study is confidentiality of the data, should it be inadvertently released. Rigorous confidentiality procedures have been developed to minimize the risk of breaches and participants will be informed of procedures to protect their confidentiality. Therefore, there is minimal risk that confidentiality will be violated. The limits of confidentiality will be explicitly described to participants by research personnel.

Although the study does not specifically inquire about risk of harm to others or child abuse, these details may emerge during the course of interviews or the intervention. Mandatory reporting laws will be explained prior to all participants as part of the consent process.

There is also a slight risk of psychological discomfort to participants from the questions asked as part of research assessments and interviews. All research personnel will be trained to respond to emotional distress resulting from the study protocol and to refer to appropriate community resources as necessary.

The ROST intervention will be delivered by group leaders (clergy) with strong interpersonal skills who will receive training and supervision from the Principal Investigator and co-Investigators (Drs. Weaver, Himle, Pfeiffer). The group leaders will have access to clinical backup from Drs. Himle and Ms. Tucker. In previous trials of CBT there have been few reported cases of uncontrollable distress; however, it is always possible that negative reactions may arise. In these circumstances, group leaders will follow our risk management protocol which involves contacting either Dr. Weaver or Dr. Himle, following through with strategies that are empathic and non-blaming, and encouraging immediate engagement with supportive close others and with ongoing professional mental health assistance.

Protection Against Risks.

Recruitment and Informed Consent. Informed consent will be procured in-person, prior to the initial baseline interview. All participants will be told that participation is voluntary and can be withdrawn at any time. Participants will also be advised that information provided will be kept confidential. Limits to confidentiality will be discussed and provided in written format (i.e. prominent suicidal or homicidal ideation with imminent risk, child abuse).

Protection Against Risk. We do not consider the time demands on participants a serious risk for two reasons. First, the informed consent procedures emphasize the fact that the interviews are voluntary and can be terminated at any time. Second, the participants will be paid a nominal fee of $25 for assessments at baseline, post-treatment, and 3-month follow-up; and $20 for completion of a qualitative interview at follow-up. Participants completing ROST will receive $10 for each session they attend. These payments compensate for

the time demands made on respondents by their participation and travel expenses. In addition, study personnel will be trained to minimize these time burdens in whatever way they can, particularly by scheduling assessment interviews at times that are convenient to respondents and encouraging them to take breaks or tend to their personal needs as they wish.

The potential risks of breached confidentiality are more serious, and we have taken a number of special precautions. First, research personnel will complete training sessions on all stages of confidentiality, including personal contact, telephone contact, and data records and management. The importance of maintaining confidentiality will be emphasized at all times. Breaches in confidentiality by staff members will be grounds for dismissal.

Participants' identifying information (i.e. name, address, phone number, email address) will be kept separate from their responses. Identification codes will be assigned to participants. These codes will also be kept separate from identifying information except for the purpose of follow-up interviews. These connections will be destroyed once the data is collected.

Concerns about confidentiality continue after the interviews are completed. Data, coded only with unique identifying code numbers, will be stored separately from identifying information. All data will be stored in locked files, accessible only to the Principal Investigator and key study personnel. All data collected via paper measures will be scanned and stored on password protected computers on the University of Michigan's secure server. REDCap will be used to electronically collect data at each session during active groups. University of Michigan has a license with REDCap and the program is HIPAA compliant. Data collected electronically will be exported from REDCap and stored on password protected computers on the University of Michigan's secure server. All published reports will contain data reported either in aggregate form (where no individual responses can be identified) or in composite individual examples that are constructed so that identification is not possible. In addition, all levels of staff will have completed the University of Michigan's web-based Program for Education and Evaluation in Responsible Research and Scholarship (PEERRS). The principal investigator and mentors have already completed certification of this training.

Based upon the mentorship team members' experience with similar studies, there is minimal risk of subjects becoming emotionally distressed by the assessment interview process or participation in the intervention. Participants are instructed that they can terminate the assessment interview at any point or refuse to answer any questions. Further, assessment interviewers will be instructed to terminate an interview whenever they feel that it is creating genuine distress for a participant. Group leaders will be trained in how to appropriately and sensitively handle distress, should it emerge during the intervention. (see distress protocol above).

Protections for Participants with Suicide Risk

The primary risk with the proposed study is suicide risk. This research will follow a comprehensive protocol for responding to suicide risk based on the University of Michigan Health System (UMHS) suicide risk assessment standards. In every case, if a participant is determined to be at risk for suicide, several steps will be followed: (1) ongoing contact with the participant will occur until risk is determined to be minimal; (2) the investigators will be informed immediately and continuously apprised of any changes/developments in the participant's risk for suicide; (3) all assessments, conversations, and steps taken with the participant to ensure safety will be thoroughly documented; (4) we will communicate with our IRB to determine the need for adverse event reporting, and any actions taken or outcomes will be reported to the IRB and NIH. All participants will be initially interviewed in-person by trained research associates who have clinical experience and graduate level mental health training. This methodology allows for intervention should suicide be a risk. Interviewing clinicians will be trained in risk assessment and will receive ongoing training throughout the course of the study. All participants will be assessed for suicide risk using the UMHS suicide risk assessment protocol. If a participant is determined to be at risk based on clinical assessment, the research associate will contact Dr. Himle or Ms. Tucker by phone or text. If risk is determined during the intervention based upon results of measures completed electronically during sessions or via participant disclosure of suicidal ideation, group leaders will contact Dr. Himle or Ms. Tucker by phone or text. In both cases, Dr. Himle or Ms. Tucker will then contact the

participant immediately and further assess suicide risk. If risk is determined to be present, the standard clinical protocol for responding to suicide risk will be implemented.

The protocol is as follows:

(1) Mild Risk (e.g., suicidal ideation present without presence of current plan, low intent, presence of hope, no current means)
a. The individual will be encouraged to call the local Psychiatric Emergency Service.
b. The individual will be encouraged to discuss feelings with family members. Should family members be present at the time of the interview, their immediate involvement will be enlisted.
c. Follow-up contact will be provided by the research team until risk is determined to be minimal.
(2) Moderate Risk (e.g., suicidal ideation present with additional risk factors: moderate intent, low hope, possible plan and/or possible means)
a. The individual will be encouraged to call the local Psychiatric Emergency Service.
b. If the individual refuses to call PES, we will enlist the assistance of a family member in doing so.
c. If the individual refuses to enlist family, or if family is not present, the individual will be encouraged to have the clinician call. Should the individual refuse, and if no one is in the home to ensure ongoing safety, the clinician will make the phone call against the individual's will.
d. A plan for removing from the home any means with which to commit suicide, preferably with the assistance of family or trusted others.
e. Continuous follow-up phone contact ensuring the participant's safety throughout the day and then on a daily basis until risk is determined to be mild. Phone calls will then occur less frequently until risk is determined to be minimal. The participant will be told at the outset of participation that, if suicide risk is present and they cannot be reached by phone, that the local safety authority or police will be called.
(3) High Risk (e.g., suicidal ideation present with several additional risk factors: high intent, no hope, a definite plan, and current means)
a. The individual will be encouraged to call the local Psychiatric Emergency Service.
b. If the individual refuses to call PES, we will enlist the assistance of a family member in doing so.
c. If the individual refuses to enlist family, or if family is not present, the individual will be encouraged to have the clinician call. Should the individual refuse, and if no one is in the home to ensure ongoing safety, the clinician will make the phone call against the individual's will. PES will send a unit or the police to the home.
d. The clinician will remain present in the home or in constant telephone contact until the participant's safety is ensured. Should the participant refuse hospitalization and it is deemed necessary, the clinician will engage police and authorities in ensuring involuntary hospitalization.
e. Any potential means with which to commit suicide will be removed from the home, preferably with the assistance of family or trusted others.
f. On-going follow-up will occur until it is determined that risk is minimal.

The comprehensive written informed consent document will outline potential limits of confidentiality based on suicide risk and on suspicion of child abuse and neglect. Participants will be notified of the clinical researcher's obligation to act in a manner that is most protective of their own safety and the safety of their children. In situations of suspected abuse and neglect, we will use procedures identical to those in place at the UMHS Department of Psychiatry.

POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE PARTICIPANT AND OTHERS

Potential Benefits Weighed Again Risk

Potential Benefits Weighed Again Risk. Participants in the study have the opportunity to: learn more about depression, co-occurring disorders, such as anxiety disorder, and its treatment, and receive an effective, guideline concordant treatment without incurring any individual costs. Furthermore, an explicit purpose of the study is to improve the accessibility and acceptability of CBT, an efficacious treatment for depression, among rural persons. Thus, participants have an improved chance to reduce their depressive symptomatology and the opportunity to share their perceptions of the intervention. Additionally, though suicide risk is a real concern in

this study, the study teams' experience researching depression suggests that asking about suicidality and having a comprehensive plan for responding to such risk holds the benefit of improved identification and treatment of persons at high risk for suicide. The potential benefits of intervening with a suicidal person are evident and represent a well-documented public health need.

The risks discussed above will all be minimized by the procedures we plan to implement as part of the data collection protocol. Burden is minimal because participants can terminate the interview whenever they begin to find it burdensome. Confidentiality risks are virtually eliminated by the special procedures adopted to separate identifying records from data files. Risks of emotional distress created by the assessment interview or intervention appear to be minimal. Nonetheless, we will include procedures to terminate assessment interviews whenever there is evidence that distress is being created. We will also have clinical back-up from study team members (e.g., Dr. Himle, Ms. Tucker) who are licensed clinical social workers and they can intervene if the assessment interview or intervention appears to create distress. Finally, all participants will be remunerated for each stage of their participation, totaling up to $255**.** In sum, potential benefits for the research far outweigh the risks for the participants. Finally, all participants will be remunerated for each stage of their participation, totaling up to $255**.** In sum, potential benefits for the research far outweigh the risks for the participants.

DATA SAFETY AND MONITORING PLAN

For the proposed project, a number of safeguards will be implemented to ensure the safety of participants and the integrity of the data, based on guidance from the NIH Notice for Data and Safety Monitoring (OD-00- 038). First, all study procedures, documents, and safety plans will be submitted and approved by the University of Michigan Medical School Institutional Review Board (MEDIRB). This will include a mechanism for reporting any adverse events to the MEDIRB and to the NIH. The UM MEDIRB reviews all adverse events reported. The study investigators will fully and promptly inform the NIH of any actions taken by the UM MEDIRB in response to adverse events.

We will establish a Data Safety Monitoring Board (DSMB) to monitor human participant protections on an ongoing basis at the University of Michigan. The DSMB is a monitoring body established in keeping with NIH guidelines for the appropriate oversight and monitoring of the conduct of clinical trials. The DSMB will convene a minimum of two times each year during the active phase of the study, to review the following: (a) research protocol and plans for data and safety monitoring, (b) adverse events and unforeseen outcomes, (c) ethical issues related to recruitment activities, (d) risk management policies and activities, and (e) intermediary data analyses. They will evaluate the progress of the proposed intervention trial through regular assessments of data quality, participant recruitment, and risk versus benefit, retention, and performance of the trial site. The DSMB will make recommendations to the IRB and study investigators concerning continuation or conclusion of the trial.

Proposed members of the DSMB include University of Michigan faculty members Dr. Matthew J. Smith and Dr. Andrew Grogan-Kaylor. We will name an additional member from outside of the University to join the board. In keeping with the "NIH Policy for Data and Safety Monitoring," additional members will be included in the DSMB or consultants will be involved as necessary to interpret the data and ensure participant safety. For instance, the expertise of a biostatistician who is uninvolved with the study could potentially be needed.
Each year, the DSMB will issue a report that summarizes:

1. (1) All serious and unexpected adverse events (e.g., inpatient hospitalizations or significant worsening of clinical status) or other unanticipated problems that involve risk to study participants or others, and whether these appeared related to the study-based interventions or research assessment protocols.
2. (2) The committee's judgments regarding the assurance of the participants' safety, privacy, and confidentiality.
3. (3) Judgments as to whether research instruments have been administered appropriately while assuring participants' confidentiality.
4. (4) The committee's review of the study's progress toward recruitment goals, quality of data, treatment adherence, and participant retention/attrition rates.

5. (5) The committee's review of new research relevant to the safety of participants or the ethics of participation (for example, new therapeutic developments).
6. (6) Its recommendations as to whether risk/benefit ratios have changed to the extent that the trial should be modified or discontinued. Specific recommendations for protocol modifications will be described, with the accompanying rationale for each.

DSMB reports will be filed immediately with the IRB, as well as with the NIH Project Officer and the NIH Office for Human Research Protections (OHRP). The reports will include the dates that the committee met and the procedures used for monitoring participants' safety, confidentiality, and data integrity. The principal investigator will take responsibility for reporting any serious and unexpected adverse events in a timely fashion directly to the DSMB and IRB. Actions taken by the IRB in response to adverse event reports will be immediately reported to the DSMB and the NIMH Project Officer and OHRP office. The principal investigator recognizes the need for regular communication between the DSMB and the IRB.