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Reducing Depressive Symptoms through Behavioral Activation in Churches: A Hybrid-2 randomized effectiveness-implementation design

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Declarations

Ethics Approval and Consent to Participate: This study was approved by the University of Arkansas for Medical Sciences (UAMS) Institutional Review Board (FWA00001119). As such the study is in compliance with the Helsinki Declaration and all study participants will provide informed consent.

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Abstract

Rural African Americans are disproportionately exposed to numerous stressors such as poverty that place them at risk for experiencing elevated levels of depressive symptoms. Effective treatments for decreasing depressive symptoms exist, but rural African Americans often fail to receive adequate and timely care. Churches have been used to address physical health outcomes in rural African American communities, but few have focused primarily on addressing mental health outcomes. Our partnership, consisting of faith community leaders and academic researchers, adapted an evidence-based behavioral activation intervention for use with rural African American churches. This 8-session intervention was adapted to include faith-based themes, Scripture, and other aspects of the rural African American faith culture (e.g. bible studies)

This manuscript describes a Hybrid-II implementation trial that seeks to test the effectiveness of the culturally adapted evidence-based intervention (Renewed and Empowered for the Journey to Overcome in Christ: REJOICE) and gather preliminary data on the strategies necessary to support the successful implementation of this intervention in 24 rural African American churches. This study employs a randomized one-way crossover cluster design to assess effectiveness in reducing depressive symptoms and gather preliminary data regarding implementation outcomes, specifically fidelity, associated with 2 implementation strategies: training only and training + coaching calls.

This project has the potential to generate knowledge that will lead to improvements in the provision of mental health interventions within the rural African American community. Further, the use of the Hybrid-II design has the potential to advance our understanding of strategies that will support the implementation of and sustainability of mental health interventions within rural African American faith communities.

1. Introduction:

African Americans living in the rural South are more likely to live in persistent poverty[1] (poverty rates of at least 20% since 1980)[2] and experience the adverse effects of poverty, such as, poor educational attainment, fewer economic opportunities, and poor housing conditions[3, 4]. In addition, rural African Americans have also endured decades of discrimination and racism[1,5, 6]. Chronic exposure to such stressors can lead to both negative physical health outcomes such as hypertension, diabetes, and obesity[5–9]as well as negative mental health outcomes. A strong relationship exists between the stress imposed by poverty and mental health such that those living with disadvantage, like rural African

Americans, may be at greater risk for developing depressive symptoms, which can lead to poor social and occupational functioning[10] (e.g. increased absenteeism and reduced productivity), poor role functioning as parents or spouses, poor management of chronic physical illnesses, and increased morbidity[11] associated with physical health conditions[12]. Recent studies indicate that up to 30% of rural African Americans sampled[13] reported clinically significant depressive symptoms compared to estimates of 10-19% found in other studies with community samples[14].

Current efforts at reducing depressive symptoms in rural areas have focused on developing practice-based interventions aimed at improving the quality of services provided. Quality improvement programs (i.e. collaborative models of care) have been shown to be efficacious and cost-effective[15–18]; however, these interventions do little to address the primary barriers experienced by rural African Americans: difficulties accessing services, stigma, and poor depression literacy (i.e. knowledge about the symptoms and treatment options for depressive symptoms)[19]. Thus, rural African Americans with elevated depressive symptoms often fail to receive adequate and timely care.

The church is one of the most trusted institutions in rural African American communities, with a long-standing history of social activism and shaping of values and community norms [20] Rural African American churches have served as community “portals” or venues through which advances in healthcare have been translated into real-world settings[21]. Given the historical and continued importance of the church and that approximately 85% of rural African Americans report at least weekly church attendance,[22] churches are an ideal conduit for a community-based intervention in this population. In partnership with community partners, a behavioral activation intervention was adapted to create the REJOICE (Renewed and Empowered for the Journey to Overcome in Christ Everyday) intervention for rural African Americans experiencing elevated depressive symptoms. The study has three main objectives: 1) test the effectiveness of the REJOICE intervention in decreasing depressive symptoms, 2) pilot two potential strategies to support the implementation of REJOICE in rural African American churches (training only and training + coaching calls), and 3) examine the sustainability of REJOICE after research support is removed.

2. Methods

2.1. Trial Design Overview

Broadly disseminating and implementing evidence-based practices has been a challenge in many communities, particularly underserved communities such as rural African American communities [23] Without adequate implementation, participants realize few benefits. Further, few studies have examined the sustainability of health promotion efforts within faith-based organizations when research support is withdrawn. Therefore, it is important to further our understanding of the strategies necessary to support the implementation and sustainability of the REJOICE intervention. Hybrid effectiveness-implementation studies increase the efficiency of translating research into practice compared to the more traditional approach of “completing” effectiveness research before beginning implementation-focused research[24] Hybrid effectiveness-implementation trials fall on a continuum of that ranges from designs that focus primarily on effectiveness outcomes (Type 1) to designs that focus

more equally on effectiveness and implementation outcomes (Type 2), to designs that focus primarily on implementation outcomes (Type 3). This article describes a Hybrid 2 Effectiveness-Implementation study that aims to test the effectiveness of REJOICE vs. an usual-care control in terms of patient outcomes (depressive symptoms) and to generate preliminary evidence on two competing implementation strategies (training only and training + coaching calls) in support of uptake and sustainability of the evidence-based depression intervention in rural faith communities. We chose a Hybrid 2 trial because although behavioral activation is evidence-based, the adaptation of behavioral activation to our population warranted a new randomized effectiveness trial at the patient level. However, given the strength of behavioral activation generally and the new context of REJOICE (churches and lay delivered), a Type 2 trial was chosen to explore the impact of implementation strategies in support of the intervention.

Churches in the REJOICE intervention arm will provide the REJOICE intervention over an 8-week period. Churches in the control arm will receive educational materials about identifying depressive symptoms and self-management options for addressing depressive symptoms. This is consistent with self-management interventions commonly utilized for individuals experiencing mild to moderate levels of depressive symptoms [25, 26]. We decided to compare REJOICE to treatment as usual as this design will allow us to evaluate whether this intervention offers an improvement over the current standard of practice in rural areas [27]. This study uses a randomized one-way crossover cluster design [28] (see Figure 1) to assess effectiveness outcomes and gather preliminary data regarding implementation outcomes associated with 2 implementation strategies: training + coaching calls (indicated by the letter a in Figure 1) and training only (indicated by the letter b in Figure 1). Churches will be recruited and trained on a rolling basis, with each church individually progressing through T0 through T3 (Figure 1). A total of 24 churches will be recruited and each church will complete recruitment activities and training of lay leaders (Time 0), and be randomized to either the REJOICE intervention arm with 2 implementation strategies (training + coaching calls) or the usual care arm (Time 1). A total of 12 churches will be randomized to the treatment arm and 12 churches will be randomized to the usual care arm. Four months after the completion of Time 1, the implementation pilot will begin. At Time 2, churches in the usual-care arm will receive the REJOICE intervention with the training implementation strategy only, whereas churches randomized to the REJOICE intervention arm will continue to receive the REJOICE intervention arm with two implementations strategies (training + coaching calls) (Time 2). Four months after Time 2, each church will receive no intervention or implementation support (Time 3).

2.2. Setting and Population

The proposed study involves African American churches in the Arkansas Delta. The Delta is a predominately rural region bordering the Mississippi River in Arkansas, Louisiana, and Mississippi. Arkansas consistently ranks among the worst in the nation on mental health indicators and has marked racial health disparities in both physical and mental health outcomes. We chose to work in the Arkansas Delta region because of the high rates of unmet need and because for the last ten years we have worked to build relationships with a wide range of community groups based in this region. Although 16% of Arkansans identify as

African American[29], the Delta region is predominantly African American. Arkansas ranks 4th in the nation on in poverty rates with 18.8% of Arkansans living in poverty during 2010. [30] In terms of mental health, Arkansas ranked 28th in the nation in 2010 on measures of adults who report having 14 or more poor mental health days (a measure indicating high risk for common mental disorders such as depression and anxiety)[31] African Americans in the Arkansas Delta are significantly more likely to report having 14 or more poor mental health days compared to other ethnicities [32, 33]

Arkansas ranks third nationally in terms of religiosity[34] A total of 74% of Arkansans believe that religion is very important in their lives, 50% attend church at least weekly, 68% pray daily, and 84% believe in God with “absolute certainty”[34] Most members of African American faith communities attend historically Black denominational traditions (59%), which include National Baptist, Convention, Methodist, and Pentecostal. Approximately 7,500 religious congregations exist in Arkansas, of which approximately 10% are characterized as Historically Black Denominational Traditions[35] The Community PIs have confirmed with their networks that the majority of rural African American congregations (approximately 60%) within the rural Arkansas Delta region have 50 or fewer members, while the remaining (40%) have from 50-150 members. Regardless of congregation size, few have a full-time administrative staff. Larger congregations (50-150 members) are more likely to have full-time pastoral staff.

2.2. Community Partnerships

Our team consists of community and academic partners who have worked closely together in the planning of this study. Community Co-Principal Investigators (Community PIs) lead the Faith Task Forces of Phillips and Jefferson Counties, which consists of over 40 churches and community organizations in the Arkansas Delta. The Faith Task Forces have been collaborating with academic partners of our team for over ten years on various NIH and USDA-funded health promotion research projects addressing mental health and health disparities. Our project is structured such that community and academic partners are involved in every stage of the research process. Community PIs work closely with the Academic Principal Investigators (PIs) to oversee the execution of the study activities. The Faith Task Forces are working closely with the academic partners of our team to refine the REJOICE intervention, recruit churches and participants, and provide on-going feedback on all aspects of the study. In addition to our local Faith Task Forces, we have a Steering Committee consisting of the academic and community PIs, two community-engaged researchers, and two community members that provides guidance about all aspects of the study.

2.3 Study Intervention:

Renewed and Empowered for the Journey to Overcome in Christ Everyday (REJOICE) REJOICE is based on behavioral activation (BA), an evidence-based psychotherapy for the treatment of depression that focuses on identifying and scheduling personally meaningful activities to reduce depression while simultaneously addressing obstacles (i.e. avoidance) to participating in identified activities[36]. Small groups of five individuals led by two lay leaders undergo an 8-session faith-based behavioral activation protocol that provides

individuals with education about identifying depressive symptoms, identifying pleasurable activities, scheduling pleasurable activities, and identifying and addressing avoidant behaviors that act as barriers to completing pleasurable activities (see Table 1).

Group sessions are held weekly for 1.5 hours for 8 sessions. Sessions are delivered within a 2-month time frame. Each session begins with a private mood-check where REJOICE leaders review participants' homework assignments and weekly mood chart. Additional details regarding the REJOICE development will be available in a forthcoming manuscript.

2.3.1 REJOICE Implementation Strategies—The REJOICE implementation strategies of 1) in-person training only and 2) in-person training + coaching calls with lay leaders arose from a previously conducted pilot of the REJOICE intervention. In the previously conducted pilot, both in-person training and coaching calls with lay leaders were used.

REJOICE leaders received 20 hours of training that provided information about the signs and symptoms of depression, the behavioral activation conceptualization of depression, behavioral strategies to address avoidance, and group facilitation skills. Leaders also participated in weekly coaching calls that provided technical support, and assistance with addressing any problems that may have impacted the weekly group sessions. In-person training of lay leaders and coaching calls were initially chosen because they have been commonly used in behavioral medicine, particularly in lay-led behavior change interventions. Preliminary results from the REJOICE pilot indicated that using training and coaching calls resulted in adequate intervention fidelity. However, community partners suggest that using both training and coaching calls to train lay leaders to deliver the intervention may not be sustainable for a resource-poor environment, such as the Arkansas Delta (J. Meyer, July 7, 2015). Indeed other evidence-based psychoeducational programs have been successfully implemented in rural areas with minimum implementation support[37]; however, this has not been confirmed in evidence-based psychotherapy interventions. Therefore, the current study seeks to test the effectiveness of using only one implementation strategy (in-person training only) vs. both implementation strategies (training +coaching calls) to determine the minimum level of implementation support necessary to ensure proper fidelity.

2.4 Identification and Recruitment of Participants:

The proposed research will recruit four waves of six churches each on a rolling basis from Years 1-2, for a total of 24 churches recruited (Time T0).

2.4.1. Church Recruitment: Community PIs and partners have extensive faith-based networks across the Arkansas Delta and will use their networks to identify potential churches with the following characteristics: 1) predominately African American congregation, 2) located in the Arkansas Delta, and 3) did not participate in the REJOICE pilot study. During our REJOICE pilot, one church dropped out of the study due to changes in their ability to offer the intervention. Due to this experience, we will over-recruit by 20% to accommodate for church attrition. Churches that are recruited over our target of 24 will be

placed on a wait-list. At the conclusion of the study, wait-list churches will be offered REJOICE intervention materials.

2.4.2 REJOICE Leader Recruitment—REJOICE leaders recruited from participating churches will directly administer the intervention. Community and academic investigators will work with the pastors of each church to recruit two lay leaders per church (for a total of 48 lay leaders across the 24 churches) using personal contacts, flyers, and announcements to churches. Lay leaders for each wave will be recruited prior to randomization of the churches in that wave. Eligibility criteria for being a lay leader will include: 1) African American; 2) age 21 and older, and 3) association with a participating church through membership or participation in church activities. Each wave of lay leaders will be accrued over a 4-month period, allowing ample time for recruitment.

2.4.3 REJOICE Group Recruitment: After churches and lay leaders are recruited and trained, community and academic investigators will support them in recruiting at least 5 individuals to participate in the study groups at their church (30 participants in each wave/5 participants per church). Eligibility criteria for participation in the REJOICE groups include: 1) African American; 2) Aged 21 and older; 3) mild to moderate levels of depressive symptoms (scores of 11 –20 on the Beck Depression Inventory-II (BDI-II)[38] 4) Free of medical problems that might contraindicate participation in a BA intervention (i.e. active intoxication (scores of 3 or more on the AUDIT-C)⁵⁰, cognitive decline (score of 4 or more on the Brief Cognitive Screener⁵¹). Individuals who are experiencing severe levels of depressive symptoms (scores of 21 or higher on BDI-II) will be excluded from the study and given a list of 20 local mental health resources. Adults interested in participating in the study will be provided a general study overview and will undergo a screening interview to determine initial eligibility. Participants will be invited to a group orientation conducted at a participating church where the project will be explained in greater detail, and eligibility confirmed. Project staff will then schedule eligible participants' baseline collection visits. From our pilot, we expect that 30% of those recruited will report elevated depressive symptoms[39], so a goal of 16 participants per church will be recruited (to ensure an adequate sample size) to form a REJOICE group.

2.5 Time 1 Clinical Effectiveness Evaluation

Effectiveness will be assessed by comparing the refined REJOICE intervention with a usual-care control group at Time 1.

2.5.1 Baseline Assessments—A trained data collector will visit the participant at a participating church or in another arranged place. The data collector will obtain informed consent and then conduct the baseline assessment in a private place. Participants will receive a monetary incentive for completing the baseline assessment. Individuals will be required to complete the baseline assessment visit to participate in the study. Baseline assessment will be conducted within two weeks prior to the start of the intervention.

2.5.2 Post-Intervention Assessment—Follow-up assessments will occur 3 months after completion of the intervention. The follow-up assessments will be conducted by data

collectors masked to group assignment and will follow the same protocol as the baseline assessment. Participants will be given a monetary incentive for completing each of the assessments. Participants will also be asked to not share information related to their group assignment with the data collector to maintain the blinding.

2.5.3 Measures—The assessment interview consists of existing instruments, which have been demonstrated in prior studies to be valid, reliable, and culturally sensitive. We will be using the BDI-II to measure depressive symptoms (our outcome of interest). The BDI-II is a widely used 21-item self-report inventory measuring the severity of depressive symptoms in both adolescents and adults. The BDI-II has been proven to be valid and reliable across different clinical populations and cultural groups[40] (See Table 2 for overview of measures).

2.5.4 T1 Analytic Plan: Descriptive data analyses will be conducted to determine distributions of key variables (i.e. socio-demographics, depressive symptoms, use of health services, health-related quality of life, functioning, self-esteem, perceptions of social support, activation, avoidance, and religious coping), calculate transformations or collapse categories, if necessary, and review data for clear anomalies. The validation of the randomization will be assessed by comparing randomized groups on participant's key demographic characteristics such as age, gender, marital status, education level, and income. For categorical measures, chi-square or Fisher's exact test will be used, as appropriate, to assess group balance while t-test or non-parametric rank tests will be used for continuous measures. If imbalances are found, we will consider adjusting the between-group analyses for potential confounders of treatment assignment. The primary analyses will follow an intent-to-treat (ITT) approach without regard to adherence to intervention protocols. Our proposed analytic approach will assess treatment efficacy based on pre/post measures of the BDI-II response variable at the conclusion of the T1 phase (see Figure 1). Our primary analysis approach will use a mixed effects linear regression model for continuous measures while adjusting for covariates which includes baseline BDI-II scores along with baseline participant's demographic characteristics. As a virtue of the study design, clustering of participants within the churches is introduced. There may be a correlation of outcomes for members of these groups that could reduce precision and power while increasing sample size requirements. This can be summarized as the design effect, or the ratio of the required sample size to the sample size that would be needed if there were no correlation of outcomes within small groups. The usage of a mixed linear regression modeling approach accounts for the correlations among the participants in the same church and will provide an estimate of the correlation. Fit by restricted maximum likelihood and implemented in SAS PROC MIXED, this method is powerful and accommodates the complex covariance structures that may arise. This method is also robust to moderate departures from multivariate normality [46].

The primary outcome of interest is evaluating differences in BDI-II scores among those individuals in the REJOICE cohort compared to those randomized into the control group during the T1 phase. Based on a pre/post assessment period with two groups, a standard method of analysis is the use of an adjusted two-sample t-test which accounts for the

intraclass correlation coefficient based on the cluster randomized control design. This simplistic approach requires a strict assumption that a unit increase in the baseline BDI-II score is always associated with a unit increase in the post-intervention BDI-II score[46]. To avoid this necessary assumption and apply a more powerful test, the BDI-II baseline scores will be used as a covariate in a mixed effects linear regression model along with key patient-level demographic characteristics with the post-intervention BDI-II scores as the primary outcome of interest. Another advantage of this analytic approach is that all available data are used in the analysis, rather than case-wise deletion if baseline or follow-up scores are missing.

All of the presented sample size and power calculations were calculated using PASS 2011 [47]. The power calculations were based on preliminary information from the REJOICE pilot data along with published literature[48–52]. From our pilot study, the average BDI-II change scores in the treatment cohort from baseline was 2.0 with a standard deviation of 7.89 while the average change scores for the control cohort was –4.0 with a standard deviation of 8.02. This resulted in a mean difference scores of 6.0 with standard deviation of 8.0 (i.e., effect size = 0.75). Furthermore, the computed intraclass correlation coefficient (ICC) was 0.056. For the current proposal, we took a conservative estimate and hypothesized a moderate effect size of 0.45 with ICC=0.075. Thus, a sample size of 24 churches per treatment group (12 REJOICE and 12 control) with 5 individuals per church achieves 85% power to detect an effect size of 0.45 with ICC=0.075 using an adjusted two-sided t-test with a significance level of 0.05. Given that our analytical approach will be based on a mixed effects linear regression model adjusting for covariates, the resulting model will subsequently increase the computed power based on an adjusted t-test.

2.6 Time 2 Implementation Pilot

The same lay leaders in T1 will lead implementation of REJOICE in T2 and T3. When lay leaders are recruited, we will ask them to commit to delivering REJOICE up to 2 times over the course of 18 months. At Time 2, each church will recruit 5 new REJOICE group participants using the same procedures for recruiting described above. After a 4 month non-intervention period, churches in the treatment condition will provide the REJOICE intervention using the implementation strategy of training + coaching calls for a second time. Churches randomized to the control group will cross-over to the treatment condition. Cross-over churches will be provided with the 20 hour training, but will not receive weekly coaching calls.

2.6.1. Time 2 Analytic Approach:

Implementation fidelity of REJOICE will be our primary outcome for this phase.: Lay leaders will be observed by a Master Trainers twice; once within the first three weeks of the intervention and again before the sixth session. Master Trainers will complete a fidelity rating form that evaluates the lay leaders on five domains: covering session content, presenting the content in clear/logical manner, exhibiting an engaging delivery, delivering the session within the time constraints, answering participant questions well, and facilitating interactions between group members on a five-point Likert Scale (1- did not deliver; 5- delivered fully). This measure has been successfully utilized to measure fidelity in other

randomized control studies of lay leader led behavioral interventions [53–55] and was adapted and utilized successfully in our pilot. Scores will be averaged to develop a single fidelity score. Because churches receiving the implementation strategy of training + coaching calls have facilitated the REJOICE groups twice and fidelity scores may be impacted by repeated facilitation, fidelity scores from T1 will be used from these churches and compared to fidelity scores of lay leaders facilitating REJOICE for the first time at T2. A standard paired two-sample t-test will be used to compare differences in fidelity scores using the analytic strategy described above.

2.7 Time 3 Sustainability Evaluation:

After a 4-month non-intervention period, enrolled churches will be asked to provide the REJOICE intervention again. However, at this time no implementation or research support will be provided in an effort to ascertain the likelihood of rural African Americans sustaining REJOICE once research support is removed (Specific Am 3). Churches that choose to provide REJOICE during T3 will be provided with intervention materials. Individual outcomes and implementation outcomes will be collected for participating churches to assess fidelity to the protocol and investigate whether clinical outcomes are consistent with outcomes found in T1.

2.7.1 Time 3 Analytic Approach: Maintenance will be calculated as a percentage of churches out of the 24 churches that choose to offer the REJOICE intervention during the 6-month maintenance period. Additionally, focus groups will be held with 1) Lay Leaders from churches that offer REJOICE during the maintenance period and 2) church leaders (i.e. clergy and ministry leaders) from churches that offer REJOICE again during the maintenance period, 3) Lay Leaders from churches that **do not** offer REJOICE again during the maintenance period, and 4) church leaders from churches that **do not** offer REJOICE again during the maintenance period. These focus groups will be used to elicit information on the importance of REJOICE to the stakeholders and barriers and facilitators to the implementation of REJOICE (both with and without support). Further, this data will provide additional information regarding the acceptability, feasibility, and impact of the implementation interventions on the likelihood of sustainability. Each group will meet once and will include 6 – 10 participants. The focus groups will last 45-90 minutes and will be recorded. To ensure our ability to fully explore the themes that emerge, we will 1) leave open the possibility to conduct additional focus groups with any stakeholder group, and 2) obtain permission during the consent process to conduct a follow-up individual interview with focus groups participants.

2.7.2 Time 3 Measures—A semi-structured interview guide will be used, whereby community and academic investigators will revise as new topics emerge from completed interviews. Interviewing from an interview guide ensures consistent inquiries with each interview, without precluding the possibility of discovery of other relevant issues [56]. Interview guides help focus the interaction while allowing unanticipated topic areas to emerge during the interview.

2.7.4: Time 3 Qualitative Analysis—Data will be analyzed using conventional content analysis techniques that are largely inductive, though not exclusively inductive, to identify themes across responses [57]. We will divide the data coding process into five steps: 1) Data Management: We will enter verbatim interview transcripts into a qualitative data analysis software package (MAXQDA) that enables researchers to mark blocks of text with thematic codes and explore relationships among codes and between codes/participant groups; 2) Open Coding: After we have conducted and transcribed four focus groups (one from each cohort), each coder will review the interview guides and interview transcripts line-by-line for each transcript and together begin to identify key emerging themes. This open coding approach allows us to discover themes that appear regularly, leading to development of initial “top-level” codes. “Top-level” codes will be discussed and confirmed with the entire community-academic investigative team and the Faith Task Forces; 3) Top-Level Coding: After community and academic partners come to a consensus on the top-level codes (key themes/categories), the coders will then apply these codes to the rest of the transcripts as they come in. To ensure coding reliability and consistency, all coders review each other’s work and discuss and resolve differences. If we discover new themes as we continue to interview and code, we will review interviews we coded previously and apply the new codes as appropriate. Results from the coding will be confirmed with the research team and with the Faith Task Forces; 4) Sub-coding: Sub-coding involves further refinement of the broad constructs represented by the top-level codes into sub-categories. Iterative coding on all transcripts continues as interviewing continues, until we reach data saturation. Results from sub-coding will be shared with the community and academic partners and refined further; 5) Axial coding: In this step, we return to the data to discover links between key themes. At this level of analysis we are working both within our domains of inquiry and between them. This involves several rounds of iterative compare-and-contrast analyses to look for these links (returning to reanalyze all data when another link emerges). Throughout all steps of the coding process, we will create “theoretical memos” representing our analytical thinking about connections of themes and codes. Through this process, we will conceptually connect codes. We will also include investigators’ impressions and hypotheses in the memos, and these memos will form the basis of the project’s reports and manuscripts. Theoretical memos will be confirmed by community and academic partners before the final steps after coding that include interpretation and drawing conclusions[56, 57] Study PIs will ultimately develop a large, segmented table with an accompanying narrative which lists, characterizes, and describes in detail the major barriers and facilitators of implementing REJOICE (including the lay leader training and coaching calls necessary). This information will be subsequently used to develop an implementation toolkit to support widespread implementation.

2.8 Dissemination

Dissemination of research findings to the participating faith communities is an essential component of the community-based participatory research approach[46, 58] In order to continue the inclusive and transparent nature of this research effort, the community and academic investigative team will work together to create and develop a community organizing strategy for providing timely and useful information to the participating faith communities on a rolling basis, which will include flyers, community forums, and

independently organized meetings and information sessions. Lay leaders at each site will serve as the local contacts. Project results will be disseminated through scientific manuscripts, conferences, community forums, and pamphlets. If the intervention is effective, we will create a toolkit with program materials that would be useful to churches interested in providing REJOICE at their church.

3. Discussion:

Though rural African Americans may be at-risk for developing elevated depressive symptoms, few studies have examined the possibility of utilizing churches as a venue through which evidence-based interventions to address depressive symptoms can be provided to this population. Preliminary work with community partners coupled results from a pilot study that suggest that addressing mental health within rural African American churches is both culturally acceptable and feasible and that the use of behavioral activation interventions may be a good fit for use within churches. This manuscript describes a recently funded Hybrid-2 Implementation trial that aims to determine the effectiveness of a culturally adapted behavioral activation intervention and to generate preliminary evidence to assess which of two strategies would best facilitate the successful implementation and sustainability of an evidence-based depression intervention in rural faith communities.

This study is not without limitations. First, although the majority of African Americans attend church, this segment of the black community may not be representative of the larger community. Black churches play an important role in African American communities, particularly in Southern rural communities, which have the highest mean levels of church attendance and participation compared to other regions in the nation[34, 35] For the purposes of our faith-based behavioral activation for rural African Americans experiencing elevated depressive symptoms, we felt that the strengths churches offered in developing and implementing efforts to address depressive symptoms outweighed the potential limits to generalizability. However, prior studies have assessed the clinical and demographic characteristics of African American congregants residing in the Arkansas Delta. Therefore, to mitigate this limitation, we will compare the demographic and clinical characteristics of participants in this study to existing data to better assess the representativeness of our sample.

Secondly, having the same lay leaders for each church deliver REJOICE repeatedly over the study's time period may serve as a confounder in implementation analyses, as lay leaders with more experience delivering REJOICE will have more 'practice' to deliver the intervention with adequate fidelity. We will mitigate this limitation by comparing implementation scores when lay leaders deliver the REJOICE intervention for the first time. Although this will not account for potential confounding across time points, having the same lay leaders from each church deliver the intervention repeatedly more realistically mirrors what typically occurs in church-delivered group programs (e.g. the same persons typically lead Sunday School, Bible studies, etc. over a period of time). Given our focus on collecting pilot data regarding feasible implementation strategies that could be sustained, we wanted to propose methods of implementation that would most closely reflect the natural 'rhythms' of the community. Notwithstanding these limitations, this project has the potential to generate

knowledge that will lead to improvements in the provision of mental health interventions within the rural African American community. Further, the use of the Hybrid-2 design has the potential to advance our understanding of strategies that will support the implementation of and sustainability of mental health interventions within rural African American faith communities.

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Figure 1.
REJOICE Hybrid 2 Implementation Trial Overview

Table 1:**REJOICE Content**

REJOICE Content	
Session Title	Session Objectives
Session 1: Welcome and Introduction	<ol style="list-style-type: none"> 1. Meet their REJOICE Leaders and fellow group members 2. Discuss the rationale for the REJOICE program 3. Understand how their mood can affect their life 4. Understand the importance of positive activities and mood
Session 2: Stress Management	<ol style="list-style-type: none"> 1. Identify common stressors individuals experience in their community 2. Understand the importance of including stress management techniques into a daily routine 3. Identify at least one stress management technique to practice at home 4. Identify at least 3 pleasurable activities to include into a daily routine
Session 3: Overcoming Barriers to Activities	<ol style="list-style-type: none"> 1. Identify barriers to completing pleasurable activities
Session 4: Coping with Racism and Discrimination	<ol style="list-style-type: none"> 1. Discuss how anger is a valid feeling in the context of racism and discrimination 2. Develop anger management skills
Session 5: Dealing with Money	<ol style="list-style-type: none"> 1. Learn how unemployment and problems with money lead to low mood 2. Identify tips and aids for handling money and finding work
Session 6: Physical and Emotional Health	<ol style="list-style-type: none"> 1. Understand the connection between physical health and emotional health 2. Understand how physical activity is important for emotional health 3. Identify ways to include physical activity in a daily routine 4. Understand how nutrition is important for emotional health 5. Identify ways to eat healthier
Session 7: REJOICE Review	<ol style="list-style-type: none"> 1. Review information covered in previous sessions
Session 8: REJOICE Commitment and Celebration	<ol style="list-style-type: none"> 1. Review information covered in previous sessions 2. Affirm commitment to focus to work daily to improve emotional health.

Table 2:

Constructs and Corresponding Measures

Construct	Measure and Source	Description of Measure
Individual Characteristics		
Socio-demographics	Age, gender, race/ethnicity, marital status, employment, education completed, income, physical health status	This scale includes 8 demographic questions that have been utilized in national surveys as well as surveys conducted in the Arkansas Delta
Depressive Symptoms	Beck Depression Inventory (BDI-II)[40]	This scale is 21 question scale that assesses the presence of depressive symptoms in the last two weeks. Scores range from 0-63 with higher scores indicating increased severity of symptoms
Use of Health Services	NCS-R mental health utilization module [41]	This scale is a part of the larger National Comorbidity Study Replication. This scale asks participants to indicate if they have ever received services for emotional or behavioral problems and the settings in which they had received these services.
Health-Related Quality of Life	CDC Healthy Days Measure[31]	The HRQOL Scale has been administered as a part of the BRFSS since 2000. The HRQOL assesses a 1) self-rated health, 2) number of recent days when physical health was not good, 3) number of recent days when mental health was not good, and 4) number of recent activity limitation days because of poor physical or mental health
Functioning	SF-8[42]	The SF-8 Health Survey asks 8 questions to measure functional health and well-being. It is a reliable and valid measure of physical and mental health that can be used across age (18 and older), disease, and treatment group. Scores are norm-based and range from 0 (lowest level of health measured) to 100(highest level of health measured)
Self-Esteem	Rosenberg Self-Esteem Scale	A 10-item scale that measures global self-worth by measuring both positive and negative feelings about the self. All items are answered using a 4-point Likert scale format ranging from strongly agree to strongly disagree
Perceptions of Social Support	Brief Social Support Scale[43]	A 27-item questionnaire designed to measure perceptions of social support and satisfaction with that social support. Each item is a question that solicits a two-part answer: Part 1 asks participants to list all the people that fit the description of the question, and Part 2 asks participants to indicate how satisfied they are, in general, with these people
Individual Behaviors		
Behavioral Activation	Behavioral Activation for Depression Scale[44]	The scale is designed to measure changes over the course of Behavioral Activation treatment. The measure has four subscales: Activation, Avoidance/Rumination, Work/School Impairment and Social Impairment subscale. Scores are summed and higher scores indicate higher levels of the subscale title (e.g., high scores on Activation subscale = more activation)
Religious Coping	RCOPE[45]	The Brief RCOPE is a 14-item measure of religious coping with major life stressors. The Brief RCOPE has two subscales: positive religious coping and negative religious coping. Items use a four-point Likert scale ranging from 0 ("not at all") to 3 ("a great deal"). Scores are summed and range from 0-21 on each subscale.