Evaluating the Feasibility and Acceptability of a Therapeutically-grounded Virtual Sister Circle for Black Women with Depressive Symptoms

Protocol Number: UCLA IRB #21-001322

National Clinical Trial (NCT) Identified Number: NCT04837573

Principal Investigator*: Kia Skrine Jeffers, PhD, RN, PHN

Grant Title: UCLA Resource Center for Minority Aging Research / Center for Health Improvement of Minority Elderly (RCMAR/CHIME)

Grant Number*: P30AG021684 and UL1TR001881

Funded by: NIA and NCATS

Version Number: Not applicable

1 July 2022

CONFIDENTIALITY STATEMENT

This document is confidential communication. Acceptance of this document constitutes agreement by the recipient that no unpublished information contained herein will be published or disclosed without prior approval of the Principal Investigator or other participating study leadership and as consistent with the NIH terms of award.

Table of Contents

STATEMENT OF COMPLIANCE

(1) The trial will be carried out in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP) and the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812).

National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.

INVESTIGATOR'S SIGNATURE

The signature below constitutes the approval of this protocol and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines, as described in the *Statement of Compliance* above.

Principal Investigator or Clinical Site Investigator:

Signed:  Date: July 1, 2022

Name*: Kia Skrine Jeffers

Title*: Principal Investigator

Investigator Contact Information

Affiliation*: University of California, Los Angeles

Address: 700 Tiverton Avenue - Box 956918, Los Angeles, CA 90095

Telephone:

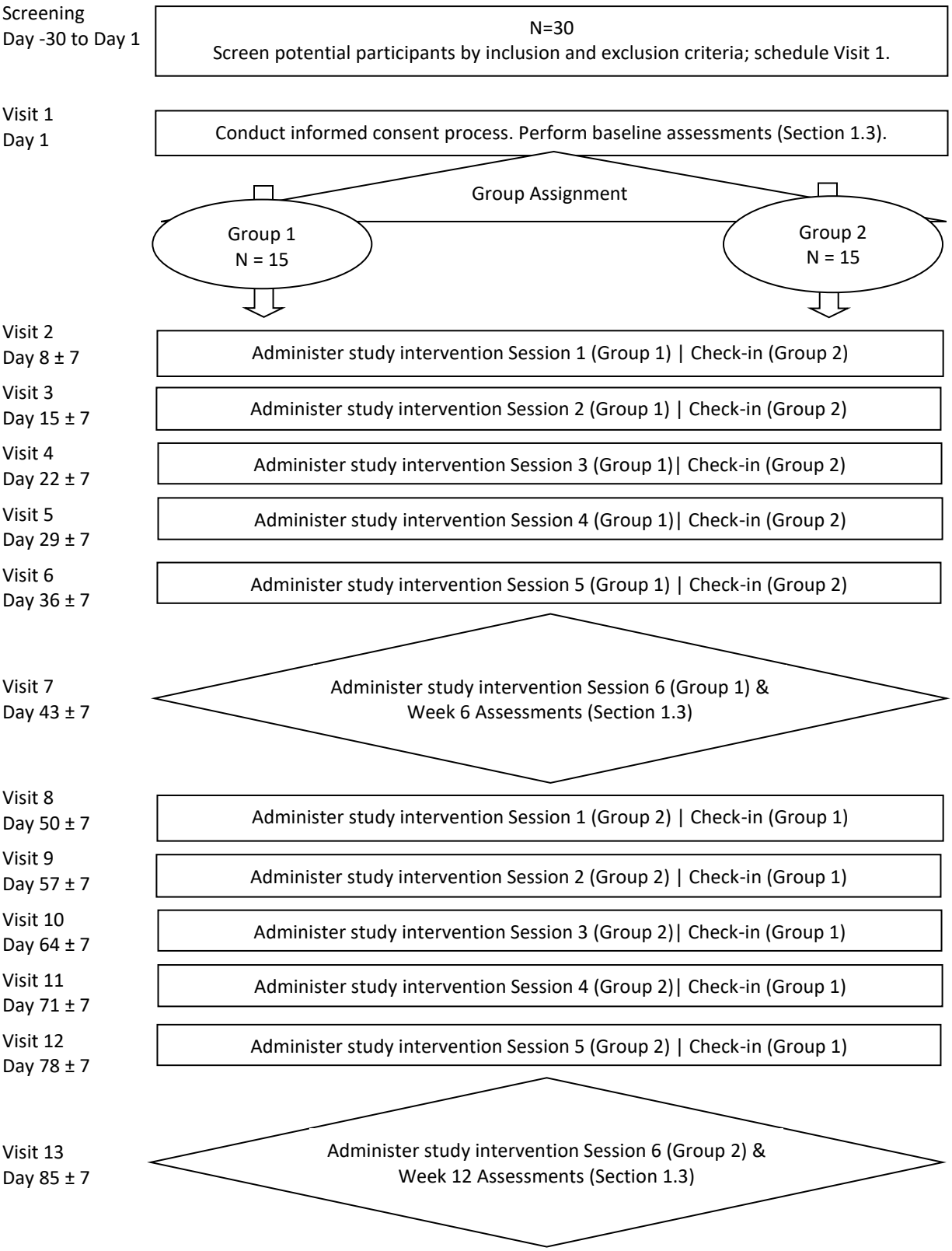
Email: kiajeffers@ucla.edu

1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	Evaluating the Feasibility and Acceptability of a Therapeutically-grounded Virtual Sister Circle for Black Women with Depressive Symptoms
Grant Number:	P30AG021684 and UL1TR001881
Study Description:	The purpose of this proposed study is to test the feasibility and acceptability of a protocol for a virtual, culturally-relevant, therapeutically-grounded, mental health Sister Circle intervention ("We See You, Sis" or WSYS) for middle- and older-aged Black women with depressive symptoms We hypothesize that the WSYS mental health intervention will be feasible and acceptable to the study sample, and the effect sizes for changes in psychological variables will be moderate to large.
Objectives*:	Primary Objective: To evaluate feasibility and acceptability of the protocol. Secondary Objectives: To describe effect sizes for changes in self-reported stress, negative emotions, and psychological flexibility among participants of the WSYS mental health intervention
Endpoints*:	Primary Endpoint: Feasibility (recruitment, retention, completion) and Acceptability (affective attitude, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness, self-efficacy). Secondary Endpoints: stress, positive and negative emotions, psychological flexibility
Study Population:	N=30 Black women in the United States Ages 40 years and older Experience depressive symptoms
Phase* or Stage:	Stage 1 of NIH Stage Model for Behavioral Intervention Development
Description of Sites/Facilities Enrolling Participants:	The study will take place via the internet/Zoom platform.
Description of Study Intervention/Experimental Manipulation:	The WSYS Virtual Sister Circle will be delivered in a group format via Zoom over the course of 12 weeks. There will be two groups of 15 women, and each group will meet weekly for 6 consecutive sessions. Group 1 will meet during weeks 1-6 of the intervention period; Group 2 will meet during weeks 7-12. Each session will last 1.5-2 hours. The intervention will be led by two trained peer leaders.
Study Duration*:	The estimated time from when the study opens to enrollment until completion of data collection is 6 months.
Participant Duration:	It will take each individual participant 3.5 months to complete all study-related tasks.

1.2 SCHEMA


Screening
Day -30 to Day 1
N=30
Screen potential participants by inclusion and exclusion criteria; schedule Visit 1.
Visit 1
Day 1
Conduct informed consent process. Perform baseline assessments (Section 1.3).
Group Assignment
Group 1
N = 15
Group 2
N = 15
Visit 2
Day 8 ± 7
Administer study intervention Session 1 (Group 1) | Check-in (Group 2)
Visit 3
Day 15 ± 7
Administer study intervention Session 2 (Group 1) | Check-in (Group 2)
Visit 4
Day 22 ± 7
Administer study intervention Session 3 (Group 1)| Check-in (Group 2)
Visit 5
Day 29 ± 7
Administer study intervention Session 4 (Group 1)| Check-in (Group 2)
Visit 6
Day 36 ± 7
Administer study intervention Session 5 (Group 1) | Check-in (Group 2)
Visit 7
Day 43 ± 7
Administer study intervention Session 6 (Group 1) &
Week 6 Assessments (Section 1.3)
Visit 8
Day 50 ± 7
Administer study intervention Session 1 (Group 2) | Check-in (Group 1)
Visit 9
Day 57 ± 7
Administer study intervention Session 2 (Group 2) | Check-in (Group 1)
Visit 10
Day 64 ± 7
Administer study intervention Session 3 (Group 2)| Check-in (Group 1)
Visit 11
Day 71 ± 7
Administer study intervention Session 4 (Group 2)| Check-in (Group 1)
Visit 12
Day 78 ± 7
Administer study intervention Session 5 (Group 2) | Check-in (Group 1)
Visit 13
Day 85 ± 7
Administer study intervention Session 6 (Group 2) &
Week 12 Assessments (Section 1.3)

1.3 SCHEDULE OF ACTIVITIES

	Screening	Visit 1 Day 1	Visit 2 Day 8 ±7	Visit 3 Day 15 ±7	Visit 4 Day 22 ±7	Visit 5 Day 29 ±7	Visit 6 Day 36 ±30	Visit 7 Day 43 ±7	Visit 8 Day 50 ±7	Visit 9 Day 57 ±7	Visit 10 Day 64 ±7	Visit 11 Day 71 ±7	Visit 12 Day 78 ±7	Visit 13 Day 85 ±7
Eligibility Determination	X													
PHQ-9	X													
Informed Consent		X												
Demographics		X												
Stressful Life Events Survey		X												
Outcome Evaluation														
Perceived Stress Scale		X						X						X
Positive & Negative Affect Schedule		X						X						X
Acceptance & Action Questionnaire II		X						X						X
Acceptability								X GRP 1						X GRP 2
Intervention Session Attendance		X	X	X	X	X	X	X	X	X	X	X	X	X
Group Assignment		X												
Adverse Events Reporting (if needed)	X	X	X	X	X	X	X	X	X	X	X	X	X	X

2 INTRODUCTION

2.1 STUDY RATIONALE

While published estimates of depression prevalence among Black women range from 10-17%[1,2]; there is additional evidence that depression is significantly underdiagnosed in this population.[3-5] Untreated depression, particularly in late life, is associated with numerous mental and physical health conditions including loneliness, anxiety, Alzheimer's disease and related dementias, morbidity from preventable cardiometabolic health conditions, accelerated aging, and suicide.[6,7,8] Depression may also contribute to racial/ethnic health disparities given the relationship between depression and cardiometabolic conditions and the strong correlation between depression and stress.[9,10] Middle- and older-aged Black women have up to 5 times greater odds of increased allostatic load (i.e., cumulative "wear and tear" from prolonged adaptation to stress) compared to their non-Hispanic White (NHW) counterparts.[11] Evidence from the scientific literature and popular media also indicate that many Black women suffer in silence from untreated depression.[12-14] New and innovative approaches are needed to address depression among middle- and older- aged Black women.

There are several, longstanding cultural factors that represent barriers to the appropriate diagnosis and treatment of depression among Black women.[15,16] Their depression-related needs can be unmet

because providers mischaracterize Black women's manifestations of depression as psychotic disorders as opposed to mood disorders–a practice that has persisted since the 19th century.[3,8,17-19] Current metrics used to diagnose depression were largely normed on NHW women and do not fully capture the experiences that contribute to depression in Black women.[18-21] Stigmas related to depression and seeking help have led to self-silencing among this group, and Black women's perception that depression is a "White person's condition" (one that Black women do not have the "luxury" of experiencing due to their doubly marginalized identities as being Black and being female) has been transferred intergenerationally.[22-25] There is a pressing need for novel interventions that address and engage Black women with depression with various treatment options.

Although engagement in formal mental health services is low relative to NHWs, middle- and older-age Black women want help for their depressive symptoms, including feelings of loneliness and social isoloation.[8] Many Black women have reported a specific interest in help which reflects their experiences as racialized, gendered people.[26] Sister Circles, informal or formal support groups for women who do not necessarily have a biological relationship with one another, have a long history of providing collective self-help in this population.[27] Sister Circles provide a trusted community for Black women to share experiences and draw upon collective strengths. Sister Circles have been used in community-based settings with Black women to address anxiety, HIV, and modifiable chronic disease risk factors.[27-29] The use of virtual Sister Circles to mitigate the loneliness and social isolation that middle- and older-aged Black women experience with depression is understudied. **The purpose of this study is to test the feasibility and acceptability of a protocol for a virtual, culturally-relevant, therapeutically-grounded, mental health Sister Circle intervention ("We See You, Sis" or WSYS) for middle- and older-aged Black women with depressive symptoms**. The intervention is informed by Acceptance and Commitment Therapy (ACT)—a cognitive-based therapy that aims to increase psychological flexibility—and is thematically derived from findings from the talk-backs of a play (*"We See You, Sis"*) that Black women viewed and discussed afterwards in the context of their unique experiences with depression.[30]

This study will use a switching replications quasi-experimental design. The 6-week, WSYS virtual mental health intervention will include 30 Black women aged 40 years and older who experience depressive symptoms. The primary outcomes of the study are feasibility (80% recruitment, 80% completion, and 75% retention) and acceptability (affective attitude, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness, self-efficacy). We hypothesize that the protocol will be feasible and acceptable. The secondary (exploratory) outcomes are to describe effect sizes for changes in self-reported stress, negative emotions, and psychological flexibility among study participants. We hypothesize that effect sizes will be moderate to large.

2.2 BACKGROUND

Depression is a leading cause of disability worldwide.[31] In the United States, depression costs an estimated $210 billion per year.[32] For every dollar spent in treating depression, almost $7 is spent on associated illnesses related to depression (e.g., anxiety, back disorders, sleep disorders, migraines), reduced work productivity, and suicide-related costs. When it persists over time, depression adversely impacts individuals' ability to function at school, work, and within their families, their ability to engage in health-promoting behaviors, their quality of life, and their physical and mental wellbeing.

There is a longstanding dearth of research on depression among Black women.[5,33,34] Recent estimates indicate that the rates of depression among non-Hispanic Black (10.4%) and White women (18%) are fairly consistent, but the chronicity of depression among the two groups is 56% and 38%, respectively.[35] **Specifically, Black women experience depression that is more chronic and more severe as compared to White women, and it is often untreated.** Prolonged and debilitating depression greatly impacts daily functioning and is associated with higher rates of psychological distress.[31,34,36] In addition

to mental health sequelae, chronic, prolonged depression is associated with increased rates of cardiometabolic conditions, as well as somatization of depressive symptoms which can manifest as headaches, back pain, and gastrointestinal issues.[1,9,10,20] In summary, untreated depression is associated with **preventable**, long-term, mental and physical suffering for Black women.

Meaningful interventions to interrupt the depression-related suffering that Black women experience are urgently needed—particularly interventions that address constellations of social and personal stressors. These include mental and social distress due to sexism and racism, identity-shifting throughout each day, managing physical health conditions, serving as the backbone and primary caretaker of their families and communities, and daily microaggressions.[16,37-39] To combat these multiple stressors, many Black women operate within Strong Black Woman schemas—i.e., outwardly personifying strength while repressing perceptions of vulnerability and suppressing fear and weakness.[35,37-40] Many Black women also engage in a silencing paradigm related to their heavy burden of stress and mental health challenges.[37] This self-silencing often results in negative emotions such as accumulated anger and frustration that they suppress throughout their life course as a means to navigate daily stress. This can be considered psychological inflexibility (rigid attempts to control psychological reactions to discomfort at the expense of values-guided action), which contributes to a general dissatisfaction with life that can feel void of purpose.

ACT is ideal for addressing depression among Black women because it is a cognitive-based therapy approach that aims to increase psychological flexibility (ability to embrace thoughts and feelings as they are while shifting attention toward chosen values, and actions linked to those values), **which can decrease stress and negative emotions**.[41,42] Unlike traditional CBT which aims to change how individuals think/feel, ACT focuses on action-planning without emphasis on changing patients' values.[43] ACT has been understudied in Black women, but this approach has demonstrated similar effectiveness to traditional CBT in depression treatment within other populations.[44] A group-based ACT approach comprised solely of Black women with depressive symptoms is optimal because of the distinct roles that Black women often assume in their families and communities, the gendered racism that they uniquely internalize, and the trusted, cultural space that they have historically held for one another in sister circles. Sister circle-type interventions have demonstrated success for populations of Black women with anxiety and other chronic health conditions.[27-29,45]

Our previous study evaluated the impact of a research-based play about Black women's experiences with depression on depression-related stigma and collective efficacy among audience participants. Our findings indicated that middle- and older-aged Black women who attended the play (n=152) largely welcome having safe spaces and opportunities to learn about, share, and heal from their experiences with depression/depressive symptoms. Salient topics shared across audience talkback groups included participants' experiences with suicidality, medication and alternative treatment options, seeking mental health services, and more. [30]

This study is conceptually informed by a model of affiliative responses to stress (Figure 1).[46] If the aims of this study are achieved, participants' untreated depressive symptoms will be addressed through engagement in the 6-week, mental health intervention, which is therapeutically informed by ACT. These therapeutic, affiliative efforts with other Black women can yield a reduction in stress and negative emotions, and an increase in psychological flexibility.

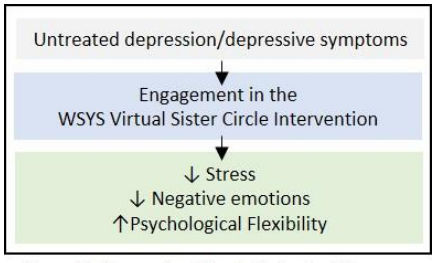


Figure 1. Conceptual Model (adapted from A Model of Affiliative Responses to Stress)

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

The potential risks to study participants include experiencing prolonged or heightened symptoms of depression (e.g., feelings of sadness or hopelessness). We will ensure that research team members are trained in communication and empathy, are present at each study session with at least one other research team member, and have a current list of resources available if an emergency arises.

2.3.2 KNOWN POTENTIAL BENEFITS

The potential benefits that participants may experience are: a reduction of stress, increase in psychological flexibility, and feeling a sense of support among a community of women who understand them. The potential benefit to society is a sense of collective efficacy to address --and possibly even treat -- depressive symptoms, peer-to-peer, in community settings. If this intervention is found to be feasible and acceptable, the utility of an evidence-based intervention that is drawn from both scientific knowledge and the experiential knowledge of the people who are most impacted, can lay the groundwork for evidence that extends the reach of mental health care in communities that may not typically access or receive adequate mental health treatment.

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

The risks to participants are reasonable in relation to anticipated benefits because the risks are minimal, and should someone become distressed, they will be supported by a community of women and a clinician (the PI) in the session, and she will be connected to resources for additional help. The knowledge gained from this study can also help support many people with untreated depressive symptoms in the community.

3 OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Primary		
To evaluate feasibility and acceptability of the protocol.	Feasibility (recruitment, retention, completion) and Acceptability (affective attitude, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness, self-efficacy).	These endpoints demonstrate feasibility of recruitment of the target sample, retention of participants, participants' adherence to the intervention, and participants' assessment of the intervention.
Secondary/Exploratory		
To describe effect sizes for changes in psychological measures.	Changes in stress, negative emotions, and psychological flexibility	These endpoints will give us a general understanding of the magnitude of the effect that the intervention has on participants' stress, positive and negative

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
		emotions, and psychological flexibility.

4 STUDY DESIGN

4.1 OVERALL DESIGN

We will use a two-group, switching replications, quasi-experimental design to achieve the study objectives of evaluating feasibility, acceptability and describing effect sizes for changes in stress, positive and negative emotions, and psychological flexibility. 30 Black women, ages 40 years and older who experience depressive symptoms, will be assigned to one of two intervention groups that will receive the intervention consecutively. Assignment will be based on participants' availability to complete the weekly intervention.

- Group 1: Intervention (weeks 1-6), No treatment (weeks 7-12)
- Group 2: No treatment (weeks 1-6), Intervention (weeks 7-12)
- A research team member will contact participants in the "No treatment" group weekly to encourage them to write in journals.

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

Although a randomized, wait-list design is a better statistical option than the two-group, switching replications quasi-experimental design, randomization of participants may negatively impact participation. Black women across the U.S. will be recruited for this virtual study, and their time zones could be a barrier to engagement if they are randomized to a group that meets at a time that does not work for them. In the real world, women would choose a group that works within the context of their lives.

4.3 JUSTIFICATION FOR INTERVENTION

A virtual mode of intervention delivery is optimal to reach Black women who physically isolate and/or remain silent about their depressive symptoms and the experiences that contribute to them. A 6-session intervention was chosen to align with the 6 core processes of ACT, and a weekly frequency was chosen to align with norms for therapeutic and support group interventions.

4.4 END-OF-STUDY DEFINITION

A participant is considered to have completed the study if she has completed the baseline assessment, at least 4 intervention sessions, and the 6- and 12-week assessments.

The end of the study is defined as completion of the Week 12 follow-up assessment shown in the Schedule of Activities (SoA), Section 1.3.

5 STUDY POPULATION

5.1 INCLUSION CRITERIA

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

1. Identify as Black or African American
2. Identify as female
3. Ages 40 years and older
4. Community-dwelling
5. Self-report of experiencing depressive symptoms/depression
6. Ability to commit to the 6-week intervention
7. Access to Zoom
8. Speak and read English

5.2 EXCLUSION CRITERIA

An individual who meets any of the following criteria will be excluded from participation in this study:

1. Self-reported diagnosis of bipolar disorder not treated with medication
2. Self-reported psychosis

These exclusion criteria are consistent with criteria for the gold standard for group-based depression interventions in the community.[52]

5.3 LIFESTYLE CONSIDERATIONS

N/A

5.4 SCREEN FAILURES

N/A

5.5 STRATEGIES FOR RECRUITMENT AND RETENTION

We will identify potential participants through social media and the study team's existing database. Flyers will be posted and promoted with targeted ads on social media platforms, and will be emailed to stakeholders who have demonstrated interest and engagement in depression-related efforts and

programming for Black women. Individuals/organizations who are recruited via email will be encouraged to forward the recruitment email to their networks. A link and QR code to complete a Qualtrics Eligibility Determination survey will be included on/with the flyer. The Qualtrics survey will be used to screen interested individuals for study eligibility. A member of the study team will contact each individual who completes the electronic screening to invite them to participate if they are eligible, or to invite them to join our mailing list for future studies if they are ineligible. A research phone number will also be provided if participants prefer to be screened by phone.

6 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

6.1 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S) ADMINISTRATION

6.1.1 STUDY INTERVENTION OR EXPERIMENTAL MANIPULATION DESCRIPTION

The WSYS Sister Circle intervention is informed by Acceptance and Commitment Therapy (ACT) and by major themes derived from our prior work. ACT has six core processes: 1) Defusion (the ability to take a step back and observe your thinking rather than get lost or tangled up in it), 2) Acceptance (allowing your experience to happen rather than avoiding or resisting it, even if it is difficult), 3) Present Moment (making contact with the present moment), 4) Observer Self (the part of you that observes the mind, as opposed to the part of you that gets lost in the mind), 5) Values (what you care about; things that are important to you; things that bring a sense of meaning, purpose, and fulfillment), and 6) Committed Action (making a commitment to move in the direction of your values despite whatever discomfort might arise as a result of doing so). Major themes that recurred across audience talk-back discussions included wanting to know what depression is and how to identify it, treatment options (therapy, medication, holistic care, traditional/indigenous methods, self-care, and gatherings for Black women to talk about depression), and suicidality and self-harm.

WEEK	ACT PROCESS	MAJOR THEME
1	Defusion	What are depressive symptoms/depression and what does it look like in our daily lives?
2	Acceptance	The actual and perceived risks of disclosing depressive symptoms
3	Present Moment	Taking medications/self-medicating
4	Observer Self	Suicide, suicidal ideation, and self-harm
5	Values	Seeking help, self-management, and self-care
6	Committed ACTion	Seeing and Being Seen, Sis

Each session will focus on one ACT process and will model how to implement the process within the context of at least one of the major themes. Participants will also have the opportunity to collectively apply the process to address challenges that are triggering, heightening, or exacerbating their current experiences with depressive symptoms. This will occur as a group or in Zoom breakout rooms. Sessions

will last 1.5-2 hours and will be structured as follows:

a) Rapport-building/check-in/grounding activity (15 min.)
b) Overview of one ACT process (15-30 min.)
c) Guided share as a group, or in small groups/pairs via breakout rooms (45-60 min.)
d) Close (15-30 min.)

6.2 FIDELITY

6.2.1 INTERVENTIONIST TRAINING AND TRACKING

The PI will train two peer facilitators who self-report histories of depression/depressive symptoms. The PI and a member of the research team will attend each session to troubleshoot problems with Zoom, to take notes on the overall process, and to provide guidance during each session as needed. Although this is a peer-led intervention, the PI will de-brief with the facilitators after each session and provide direction as needed for the next session.

6.3 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

There will be no randomization or blinding in this quasi-experimental study. Participants will be assigned to groups based on their availability to attend all six intervention sessions.

6.4 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION ADHERENCE

Attendance will be tracked at each study visit. Completing each study questionnaire and focus group is an expected part of participation in the study.

6.5 CONCOMITANT THERAPY

N/A

6.5.1 RESCUE THERAPY

N/A

7 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 DISCONTINUATION OF STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

When a participant discontinues from the study, the data to be collected at the time of study intervention discontinuation will include the following:

- The reason(s) for discontinuing
- If the participant is due to complete assessments within 2 weeks of discontinuing the study intervention, those assessments will be administered at the time of discontinuation; if the next scheduled assessments are more than 2 weeks from the discontinuation date, the discontinued participant will wait for the next scheduled assessment. Thereafter, the participant will be included in all future scheduled assessments, even though not participating in the intervention.

7.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants are free to withdraw from participation in the study at any time upon request.
An investigator may discontinue a participant from the study for the following reasons:

- Any event or medical condition or situation occurs such that continued collection of follow-up study data would not be in the best interest of the participant or might require an additional treatment that would confound the interpretation of the study
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

The reason for participant discontinuation or withdrawal from the study will be recorded on a case report form. Participants who sign the informed consent form and are assigned to a group but discontinue or withdraw from the study will not be replaced.

7.3 LOST TO FOLLOW-UP

A participant will be considered lost to follow-up if she fails to return for 3 intervention sessions and study staff are unable to contact the participant after at least 3 attempts.

The following actions must be taken if a participant fails to join a virtual intervention session:

- A study team member will attempt to contact the participant, counsel the participant on the importance of attending the intervention sessions, and ascertain if the participant wishes to and/or should continue in the study
- Before a participant is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the participant (where possible, 3 telephone calls, texts, and emails). These contact attempts will be documented in the study file.

- Should the participant continue to be unreachable, she will be considered to have withdrawn from the study with a primary reason of "unknown".

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 ENDPOINT AND OTHER NON-SAFETY ASSESSMENTS

Screening will take place within 30 days preceding Day 1 of the study. Potential participants can choose to be screened via Qualtrics or by phone. Items from the screening questionnaire (Eligibility Determination Form) include:

- Race
- Gender
- Age today
- Housing status
- Reliable access to Zoom via computer, tablet, or phone
- Availability to commit to at least (1) six-week intervention
- PHQ-9 (will be used to identify the presence of at least one depressive symptom, not to assess depression severity or for diagnostic purposes).
- Speak and read English

Any potential participant who does not self-identify as Black/African American, female, is at least 40 years of age, is community-dwelling, has reliable access to Zoom, can commit to at least (1) six-week intervention, and does not self-report at least one depressive symptom will be ineligible.

Baseline assessments will be conducted on Day 1 of the study and will include the following:

- Demographic data (age, sexual orientation, marital status, education level, housing status, employment status, health insurance status, income)
- Stressful Life Event Scale (SLE)[53]
    - This survey measures 4 clusters of events that occurred *in the last 12 months* (work-related, financial, relationship, and bereavement). For each event, participants will be asked to rate the perceived impact of the event on their life ("happened, bad effect"; "happened, but no effect"; "happened, good effect"; "did not happen"). Events that "happened, bad effect" will be scored with a '1', all other responses will be scored with a '0'.
- The Perceived Stress Scale (PSS)
    - This survey assesses subjective psychosocial stress.[56] Respondents rate items on a scale from 0 to 4; higher scores indicate greater levels of perceived stress.
- Positive and Negative Affect Schedule (PANAS)
    - This survey is the most widely used scale to assess positive and negative affect and has been validated in an African American sample. PANAS consists of 20 words that describe emotions felt in the last week and are self-rated from very slightly/not at all to extremely (1-5).[57,58]
- Acceptance and Action Questionnaire II (AAQ-II)

- This survey is a validated 7-item measure of psychological flexibility that ranges from "never true" to "always true" (0-7). Items are summed. [59]

The PSS, PANAS, and AAQ-II will also be administered at Weeks 6 and 12 for Groups 1 and 2, respectively.

A log of intervention attendance will be maintained for each intervention session visit to track and evaluate the study's primary endpoints (recruitment, retention, and completion).

The structured focus group interview guide that will be delivered on Week 6 and Week 12 for Groups 1 and 2, respectively is derived from the Theoretical Framework of Acceptability, and consists of the following questions:

1) How do you feel about the Sister Circle intervention? (Affective attitude)
2) What amount of effort was required to participate in this intervention? (Burden)
3) To what extent did this Sister Circle fit with your value system? (Ethicality)
4) What do you understand about the Sister Circle, ACT, and how they work together to help Black women who experience depressive symptoms? (Intervention coherence)
5) What, if anything, did you have to give up in order to participate in the Sister Circle for 6 weeks? (Opportunity costs)
   Probe: This includes events, responsibilities, interests, and your own values.
6) To what extent did the Sister Circle achieve its purpose? (Perceived effectiveness)
7) How confident are you that you can live a values-driven life? (Self-efficacy)

8.2 SAFETY ASSESSMENTS

N/A

8.3 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

8.3.1 DEFINITION OF ADVERSE EVENTS

This protocol uses the definition of adverse event from 21 CFR 312.32 (a): any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related.

8.3.2 DEFINITION OF SERIOUS ADVERSE EVENTS

We use the following definition for serious adverse event: "Any adverse event that: results in death, is life threatening, or places the participant at immediate risk of death from the event as it occurred, requires or prolongs hospitalization, causes persistent or significant disability or incapacity, results in congenital anomalies or birth defects, is another condition which investigators judge to represent significant hazards."

8.3.3 CLASSIFICATION OF AN ADVERSE EVENT

8.3.3.1 SEVERITY OF EVENT

The following guidelines will be used to describe severity of adverse events (AEs).

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious".

8.3.3.2 RELATIONSHIP TO STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

All adverse events (AEs) will have their relationship to study procedures, including the intervention, assessed by the PI, an appropriately-trained clinician. The degree of certainty about causality will be graded using the categories below.

- **Definitely Related** – There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out. The clinical event, including an abnormal laboratory test result, occurs in a plausible time relationship to study procedures administration and cannot be explained by concurrent disease or other drugs or chemicals. The response to withdrawal of the study procedures should be clinically plausible. The event must be pharmacologically or phenomenologically definitive.
- **Probably Related** – There is evidence to suggest a causal relationship, and the influence of other factors is unlikely. The clinical event, including an abnormal laboratory test result, occurs within a reasonable time after administration of the study procedures, is unlikely to be attributed to concurrent disease or other drugs or chemicals, and follows a clinically reasonable response on withdrawal.
- **Possibly Related** – There is some evidence to suggest a causal relationship (e.g., the event occurred within a reasonable time after administration of study procedures). However, other factors may have contributed to the event (e.g., the participant's clinical condition, other concomitant events). Although an AE may rate only as "possibly related" soon after discovery, it can be flagged as requiring more information and later be upgraded to "probably related" or "definitely related", as appropriate.
- **Remotely related** – A clinical event, including an abnormal laboratory test result, whose temporal relationship to study procedures administration makes a causal relationship improbable (e.g., the event did not occur within a reasonable time after administration of the study procedures) and in which other drugs or chemicals or underlying disease provides plausible explanations (e.g., the participant's clinical condition, other concomitant treatments).
- **Not Related** – The AE is completely independent of study procedures administration, and/or evidence exists that the event is definitely related to another etiology. There must be an alternative, definitive etiology documented by the clinician.]

8.3.3.3 EXPECTEDNESS

A clinician with appropriate expertise in depression will be responsible for determining whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study procedures.

8.3.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during study visits, or may be directly reported to the PI or IRB through a phone call.

All AEs will be captured on the appropriate case report form. Information to be collected includes event description, time of onset, clinician's assessment of severity, relationship to study procedures (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study will be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

Any psychiatric condition that is present at the time that the participant is screened will be considered as baseline and not reported as an AE. However, if the study participant's condition deteriorates at any time during the study, it will be recorded as an AE.

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. Documentation of onset and duration of each episode will be maintained for AEs characterized as intermittent.

A member of the study team will record events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit, the investigator will inquire about the occurrence of AE/SAEs since the last visit. Events will be followed for outcome information until resolution or stabilization.

8.3.5 ADVERSE EVENT REPORTING

We will monitor the following AEs:

- Increased stress
- Inability to cope
- Suicidal ideation **not requiring intervention** (e.g., a general wish to die but with no plan of inflicting self-harm to kill oneself.)

	WHEN TO CONTACT
Dr. Kia Skrine Jeffers, PI	**IMMEDIATELY**
Dr. O. Kenrik Duru	**IMMEDIATELY**
Dr. Ken Wells	**IMMEDIATELY**
Dr. Holli DeVon, Safety Officer	**WITHIN 7 DAYS** **or** ***If unanticipated and related to the intervention*** **WITHIN 48 HOURS OF KNOWLEDGE OF EVENT**

Cristina Punzalan, RCMAR/CHIME	**WITHIN 48 HOURS OF KNOWLEDGE OF EVENT**
Paul Lillig, UCLA IRB	**WITHIN 10 DAYS**
NIH/NIA	***If unanticipated and related to the intervention*** **WITHIN 48 HOURS OF KNOWLEDGE OF EVENT**

8.3.6 SERIOUS ADVERSE EVENT REPORTING

In consultation with the PI, a trained member of the study team will be responsible for conducting an evaluation of a serious adverse event and shall report the results of such evaluation to the NIH and the reviewing Institutional Review Board (IRB) as soon as possible, but in no event later than 10 working days after the investigator first learns of the event.

We will monitor the following SAEs:

- Suicide attempt or ideation **requiring intervention** (e.g., a current, specific desire to inflict self-harming behaviors that will produce a fatal outcome)

	WHEN TO CONTACT
Dr. Kia Skrine Jeffers, PI	**IMMEDIATELY**
Dr. O. Kenrik Duru	**IMMEDIATELY**
Dr. Ken Wells	**IMMEDIATELY**
Dr. Holli DeVon, Safety Officer	***If a death occurs*** **WITHIN 24 HOURS OF KNOWLEDGE OF EVENT**
Cristina Punzalan, RCMAR/CHIME	**IMMEDIATELY**
Paul Lillig, UCLA IRB	**WITHIN 3 DAYS**
NIH/NIA	***If a death occurs*** **WITHIN 24 HOURS OF KNOWLEDGE OF EVENT**

8.3.7 REPORTING EVENTS TO PARTICIPANTS

N/A

8.3.8 EVENTS OF SPECIAL INTEREST

N/A

8.3.9 REPORTING OF PREGNANCY

N/A

8.4 UNANTICIPATED PROBLEMS

8.4.1 DEFINITION OF UNANTICIPATED PROBLEMS

This protocol uses the definition of Unanticipated Problems as defined by the Office for Human Research Protections (OHRP). OHRP considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets all of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

8.4.2 UNANTICIPATED PROBLEMS REPORTING

The investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB) RCMAR/CHIME Team, Dr. Kenneth Wells, and the Safety Officer. The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number
- A detailed description of the event, incident, experience, or outcome
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP

To satisfy the requirement for prompt reporting, UPs will be reported using the appropriate timelines noted in Section 8.3.5 and 8.3.6.

8.4.3 REPORTING UNANTICIPATED PROBLEMS TO PARTICIPANTS

N/A

9 STATISTICAL CONSIDERATIONS

9.1 STATISTICAL HYPOTHESES

- Primary Endpoints: feasibility and acceptability

We hypothesize that the intervention will be feasible and acceptable. Descriptive statistics and qualitative description will be analyzed after Week 12.

- Secondary Endpoint(s): changes in stress, positive and negative emotions, psychological flexibility

We will describe effect sizes for each variable, and we hypothesize that moderate to strong effects will be observed. Data will be collected at baseline, Week 6 and Week 12 and analyzed after Week 12.

9.2 SAMPLE SIZE DETERMINATION

We will utilize convenience and snowball sampling to recruit 30 participants for the study. Our target sample size is 30 to account for the size of each intervention group (not too large for adequate participant engagement; not too small to sufficiently evaluate feasibility and acceptability) and attrition.

9.3 POPULATIONS FOR ANALYSES

In order to evaluate feasibility and acceptability of the intervention, all participants who enroll in the study will be included in the analysis.

9.4 STATISTICAL ANALYSES

9.4.1 GENERAL APPROACH

Primary Endpoints: (Feasibility) Descriptive statistics will be represented in percentages, means and standard deviations. (Acceptability) Qualitative description and descriptive statistics, as appropriate, will be used to represent acceptability. Procedural and interpretive rigor will be maintained by reflecting participant feedback back to participants to ensure the study team captures the meanings as intended.

Secondary Endpoints: Adjusted p-values for multiple comparisons, effect sizes, and 95% CIs will be calculated for each analysis.

9.4.2 ANALYSIS OF THE PRIMARY ENDPOINT(S)

Primary Endpoints: Feasibility will be assessed with 3 quantitative variables (recruitment, retention, and completion) and 1 qualitative variable (acceptability).

- Recruitment: # enrolled/# eligible
- Retention: # retained in the study/number enrolled
- Completion: # of session visits completed/# total session visits for group.
- The interview guide for our Acceptability measure can be found in Section 8.1.

9.4.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

Mean change for each variable will be calculated. We will run 3 analyses to describe effects of the intervention for each variable (stress, negative emotions, and psychological flexibility).

1) Compare Group 1 and Group 2 at Week 6, with an independent-samples t-test for each measure
2) Pool both groups and, for each stress measure, utilize a paired t-test to evaluate the overall change from the start of the intervention (Baseline for Group 1, Week 6 for Group 2) to the end of the intervention (Week 6 for Group 1, Week 12 for Group 2)
3) Evaluate if the effects are sustained from Weeks 6 to 12 for Group 1 using paired t-tests.

9.4.4 SAFETY ANALYSES

N/A

9.4.5 BASELINE DESCRIPTIVE STATISTICS

Intervention groups will be compared on baseline characteristics described in Section 8.1, Baseline Assessments.

9.4.6 PLANNED INTERIM ANALYSES

N/A

9.4.7 SUB-GROUP ANALYSES

No sub-group analyses will be conducted because of the small sample size.

9.4.8 TABULATION OF INDIVIDUAL PARTICIPANT DATA

Individual participant data is not expected to be listed by measure and time point.

9.4.9 EXPLORATORY ANALYSES

No additional exploratory analyses are expected to be conducted.

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

10.1.1 INFORMED CONSENT PROCESS

10.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

Consent forms describing in detail the study intervention, study procedures, and risks will be given to the participant and written documentation of informed consent will be completed prior to starting the study intervention. The following consent materials are submitted with this protocol:

- Study Information Sheet
- Qualtrics Informed Consent Form

10.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

After determining eligibility, potential participants will be emailed the following to learn more about the study and to complete the informed consent form if they would like to enroll in the study:

"Thank you for your interest in participating in the WSYS Virtual Sister Circle Study. To enroll in the study, please complete the following two steps:

1) Read the attached Study Information Sheet.
2) Complete this *Consent Form* to participate in the study.

Please contact Dr. Kia Skrine Jeffers, Principal Investigator, if you have any questions. Dr. Skrine Jeffers can be reached by *email* or phone (424) 272-5909.

In healing and sisterhood,

-The WSYS Virtual Sister Circle Study Team"

10.1.2 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to study participants, investigator, funding agency, and regulatory authorities. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants, the Institutional Review Board (IRB), and funding agency and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance of study staff to the protocol (ie, significant protocol violations)
- Data that are not sufficiently complete and/or evaluable
- Determination of futility

The study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the funding agency, , or other relevant regulatory or oversight bodies (OHRP, DSMB).

10.1.3 CONFIDENTIALITY AND PRIVACY

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, the safety and oversight monitor(s), and the funding agency. This confidentiality is extended to the data being collected as part of this study. Data that could be used to identify a specific study participant will be held in strict confidence within the research team. No personally-identifiable information from the study will be released to any unauthorized third party without prior written approval of the funding agency.

All research activities will be conducted in as private a setting as possible.

The study monitor, other authorized representatives of the funding agency, representatives of the Institutional Review Board (IRB), regulatory agencies or representatives from companies or organizations supplying the product, may inspect all documents and records required to be maintained by the investigator for the participants in this study. The clinical study site will permit access to such records.

The study participant's contact information will be securely stored at the clinical site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, Institutional policies, or funding agency requirements.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored on a secure, University of California, Los Angeles network. This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used by research staff will be secured and password protected. At the end of the study, all study databases will be de-identified and archived at University of California, Los Angeles.

Measures Taken to Ensure Confidentiality of Data Shared per the NIH Data Sharing Policies
It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public (see *https://grants.nih.gov/policy/sharing.htm*). The PI will ensure all mechanisms used to share data will include proper plans and safeguards for the protection of privacy, confidentiality, and security for data dissemination and reuse (e.g., all data will be thoroughly de-identified and will not be traceable to a specific study participant). Plans for archiving and long-term preservation of the data will be implemented, as appropriate.

Certificate of Confidentiality
To further protect the privacy of study participants, the Secretary, Health and Human Services (HHS), has issued a Certificate of Confidentiality (CoC) to all researchers engaged in biomedical, behavioral, clinical or other human subjects research funded wholly or in part by the federal government. Recipients of NIH funding for human subjects research are required to protect identifiable research information from forced disclosure per the terms of the NIH Policy (see *https://humansubjects.nih.gov/coc/index*). As set forth in 45 CFR Part 75.303(a) and NIHGPS Chapter 8.3, recipients conducting NIH-supported research covered by this Policy are required to establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal statutes, regulations, and the terms and conditions of award. It is the NIH policy that investigators and others who have access to research records will not disclose identifying information except when the participant consents or in certain instances when federal, state, or local law or regulation requires disclosure. NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate issued by this Policy.

10.1.4 FUTURE USE OF STORED SPECIMENS AND DATA

Data collected for this study will be analyzed and stored on the secure, University of California, Los Angeles server. After the study is completed, the de-identified, archived data will continue to be stored on the secure, University of California, Los Angeles server, for use by the study team.

10.1.5 KEY ROLES AND STUDY GOVERNANCE

Principal Investigator	**Safety Officer**
Kia Skrine Jeffers, PhD, RN, PHN Assistant Professor	Holli DeVon, PhD, RN, FAHA, FAAN Associated Dean for Research; Audrienne H. Moseley Endowed Chair in Community Research; Professor
University of California, Los Angeles	University of California, Los Angeles
Factor Building 700 Tiverton Ave. Los Angeles, CA 90095	Factor Building, Room 2-244 700 Tiverton Ave. Los Angeles, CA 90095
310-267-0483	310-794-1582
kiajeffers@ucla.edu	hdevon@sonnet.ucla.edu

STEERING COMMITTEE
UCLA RCMAR/CHIME

10.1.6 SAFETY OVERSIGHT

Safety oversight will be under the direction of a Data and Safety Monitoring Board (DSMB)/Safety Monitoring Committee (SMC) composed of individuals with the appropriate expertise, including conducting NIH-funded clinical trials. Members of the SMC will be independent from the study conduct and free of conflict of interest. The SMC will meet at least semiannually to assess safety and efficacy data from each arm of the study. The SMC will operate under the rules of an approved charter that will be written and reviewed at the organizational meeting of the DSMB. At this time, each data element that the SMC needs to assess will be clearly defined. The DSMB will provide its input to the National Institutes of Health staff as requested.

10.1.7 CLINICAL MONITORING

Clinical site monitoring will be conducted to ensure that the rights and well-being of trial participants are protected, that the reported trial data are accurate, complete, and verifiable, and that the conduct of the trial is in compliance with the currently approved protocol/amendment(s), with International Council on Harmonisation Good Clinical Practice (ICH GCP), and with applicable regulatory requirement(s). Monitoring activities will be as follows:

The Principal Investigator will be responsible for ensuring participants' safety on a daily basis. Dr. Duru (Co-I), Dr. Wells (study mentor), and the Safety Officer will also monitor participant safety, confidentiality procedures, and the quality of data collection, management, and analyses. The PI, and Drs. Duru and Wells will meet either in-person or by Zoom during week 3 of each group's 6-week intervention. Safety reports will be sent to the Safety Officer at least twice during the 1-year pilot, and will include a detailed analysis of study progress, data and safety issues.

10.1.8 QUALITY ASSURANCE AND QUALITY CONTROL

The clinical site will perform internal quality management of study conduct, data collection, documentation and completion.

Quality control (QC) procedures will be implemented as follows:

Informed consent --- Study staff will review both the documentation of the consenting process as well as the completed consent documents. This review will evaluate compliance with GCP, accuracy, and completeness. Feedback will be provided to the study team to ensure proper consenting procedures are followed.

Source documents and the electronic data --- Data will be initially captured on source documents (see Section 10.1.9, Data Handling and Record Keeping) and will ultimately be entered into the study database. To ensure accuracy site staff will compare a representative sample of source data against the database, targeting key data points in that review.

Intervention Fidelity — Consistent delivery of the study interventions will be monitored throughout the intervention phase of the study. Procedures for ensuring fidelity of intervention delivery are described in Section 6.2.1, Interventionist Training and Tracking.

Protocol Deviations – The study team will review protocol deviations on an ongoing basis and will implement corrective actions when the quantity or nature of deviations are deemed to be at a level of concern.

Should independent monitoring become necessary, the PI will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the funding agency, and inspection by local and regulatory authorities.

10.1.9 DATA HANDLING AND RECORD KEEPING

10.1.9.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection will be the responsibility of the clinical trial staff at the site under the supervision of the site investigator, Dr, Kia Skrine Jeffers. The investigator will be responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All source documents will be completed in a neat, legible manner to ensure accurate interpretation of data.

Hardcopies of the study visit worksheets will be provided for use as source document worksheets for recording data for each participant consented/enrolled in the study. Data recorded in the electronic case report form (eCRF) derived from source documents will be consistent with the data recorded on the source documents.

Clinical data (including adverse events (AEs) will be entered into the University of California, Los Angeles Qualtrics program, a 21 CFR Part 11-compliant data capture system provided by the University of California, Los Angeles. The data system includes password protection and internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate.

10.1.9.2 STUDY RECORDS RETENTION

Study documents will be retained for a minimum of 2 years after the last approval of a marketing application in an International Council on Harmonisation (ICH) region and until there are no pending or contemplated marketing applications in an ICH region or until at least 2 years have elapsed since the formal discontinuation of clinical development of the study intervention. These documents should be retained for a longer period, however, if required by local regulations. No records will be destroyed without the written consent of the funding agency, if applicable. It is the responsibility of the funding agency to inform the investigator when these documents no longer need to be retained.

10.1.10 PROTOCOL DEVIATIONS

This protocol defines a protocol deviation as any noncompliance with the clinical trial protocol, International Council on Harmonisation Good Clinical Practice (ICH GCP), or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions will be developed by the site and implemented promptly.

These practices are consistent with ICH GCP:

- Section 4.5 Compliance with Protocol, subsections 4.5.1, 4.5.2, and 4.5.3
- Section 5.1 Quality Assurance and Quality Control, subsection 5.1.1
- Section 5.20 Noncompliance, subsections 5.20.1, and 5.20.2.

It will be the responsibility of the site investigator, Dr. Kia Skrine Jeffers, to use continuous vigilance to identify and report deviations within 3 working days of identification of the protocol deviation, or within 7 working days of the scheduled protocol-required activity. All deviations will be addressed in study source documents, reported to UCLA RCMAR/CHIME. Protocol deviations will be sent to the reviewing Institutional Review Board (IRB) per their policies. The site investigator will be responsible for knowing and adhering to the reviewing IRB requirements.

10.1.11 PUBLICATION AND DATA SHARING POLICY

This study will be conducted in accordance with the following publication and data sharing policies and regulations:

National Institutes of Health (NIH) Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals.

10.1.12 CONFLICT OF INTEREST POLICY

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial. The study leadership in conjunction with the NIH/NIA has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

10.2 ADDITIONAL CONSIDERATIONS

N/A

10.3 ABBREVIATIONS AND SPECIAL TERMS

AE	Adverse Event
CFR	Code of Federal Regulations
CMP	Clinical Monitoring Plan
COC	Certificate of Confidentiality
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
DCC	Data Coordinating Center
DHHS	Department of Health and Human Services

DSMB	Data Safety Monitoring Board
DRE	Disease-Related Event
EC	Ethics Committee
eCRF	Electronic Case Report Forms
FFR	Federal Financial Report
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Council on Harmonisation
ICMJE	International Committee of Medical Journal Editors
IRB	Institutional Review Board
ISM	Independent Safety Monitor
MOP	Manual of Procedures
NCT	National Clinical Trial
NIH	National Institutes of Health
NIH IC	NIH Institute or Center
OHRP	Office for Human Research Protections
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
RCMAR/CHIME	Resource Center for Minority Aging Research/Center for Health Improvement of Minority Elderly
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SMC	Safety Monitoring Committee
SOA	Schedule of Activities
UCLA	University of California, Los Angeles
UP	Unanticipated Problem
US	United States
WSYS	We See You, Sis

10.4 PROTOCOL AMENDMENT HISTORY

*The table below is intended to capture changes of IRB-approved versions of the protocol, including a description of the change and rationale. A **Summary of Changes** table for the current amendment is located in the **Protocol Title Page**.*

Version	Date	Description of Change	Brief Rationale

11 REFERENCES

1. Sternthal MJ, Slopen N, Williams DR. Racial Disparities In Health: How Much Does Stress Really Matter? *Du Bois Rev.* 2011;8(1):95-113. PMC5993442
2. Lacey KK, Parnell R, Mouzon DM, et al. The Mental Health Of US Black Women: The Roles Of Social Context And Severe Intimate Partner Violence. *BMJ Open.* 2015;5(10):e008415. PMC4611204
3. Lawson WB, Hepler N, Holladay J, Cuffel B. Race As A Factor In Inpatient And Outpatient Admissions And Diagnosis. *Hosp Community Psychiatry.* 1994;45(1):72-74.
4. Sohail Z, Bailey RK, Richie WD. Misconceptions Of Depression In African Americans. *Front Psychiatry.* 2014;5:65. PMC4064454
5. Carrington CH. Clinical Depression In African American Women: Diagnoses, Treatment, And Research. *J Clin Psychol.* 2006;62(7):779-791.
6. U.S. Department of Health and Human Services. *Chronic Disease & Mental Health*. 2019. *https://www.nimh.nih.gov/health/publications/chronic-illness-mental-health/index.shtml*. Accessed March 25, 2021.
7. Lindqvist D, Simon NM, Wolkowitz OM. Chapter 19 - Is Depression Associated With Accelerated Aging? Mechanisms and Implications. In: Quevedo J, Carvalho AF, Zarate CA, eds. *Neurobiology of Depression.* Academic Press; 2019:207-229.
8. Akinyemi E, Watkins DC, Kavanagh J, Johnson-Lawrence V, Lynn S, Kales HC. A Qualitative Comparison Of DSM Depression Criteria To Language Used By Older Church-Going African-Americans. *Aging Mental Health.* 2018;22(9):1149-1155.
9. Bădescu SV, Tătaru C, Kobylinska L, et al. The Association Between Diabetes Mellitus And Depression. *J Med Life.* 2016;9(2):120-125. PMC4863499
10. Tafet GE, Nemeroff CB. The Links Between Stress and Depression: Psychoneuroendocrinological, Genetic, and Environmental Interactions. *J Neuropsychiatry Clin Neurosc.* 2016;28(2):77-88.
11. Geronimus AT, Hicken M, Keene D, Bound J. "Weathering" And Age Patterns Of Allostatic Load Scores Among Blacks And Whites In The United States. *Am J Public Health.* 2006;96(5):826-833. PMC1470581
12. Jack DC, Dill D. The Silencing The Self Scale: Schemas Of Intimacy Associated With Depression In Women. *Psychology of Women Quarterly.* 1992;16(1):97-106.
13. Pickens J. Depression And The Black Superwoman Syndrome. In *Ebony.* November 13, 2017. *https://www.ebony.com/health/depression-black-superwoman-syndrome-real/*. Accessed March 25, 2021.
14. Williams T. *Black Pain: It Just Looks Like We're Not Hurting.* New York City: Scribner; 2009.
15. Das AK, Olfson M, McCurtis HL, Weissman MM. Depression In African Americans: Breaking Barriers To Detection And Treatment. *J Fam Prac.* 2006;55(1):30-39.
16. Jones MS, Womack V, Jérémie-Brink G, Dickens DD. Gendered Racism and Mental Health among Young Adult U.S. Black Women: The Moderating Roles of Gendered Racial Identity Centrality and Identity Shifting. *Sex Roles. (*2021). https://doi.org/10.1007/s11199-020-01214-1
17. Baker FM, Bell CC. Issues In The Psychiatric Treatment Of African Americans. *Psychiatr Serv.* 1999;50(3):362-368.
18. Zhang A, Gary F. Discord Of Measurements In Assessing Depression Among African Americans With Cancer Diagnoses. *Int J Cult Ment Health.* 2013;6(1):58-71.
19. Payne JS. Influence of Race and Symptom Expression on Clinicians' Depressive Disorder Identification in African American Men. *J Society Soc Work Res.* 2012;3(3):162-177. *https://psycnet.apa.org/doi/10.5243/jsswr.2012.11*

20. George LK, Lynch SM. Race Differences In Depressive Symptoms: A Dynamic Perspective On Stress Exposure And Vulnerability. *J Health Soc Behav.* 2003;44(3):353-369.
21. Walton QL, Boone C. Voices Unheard: An Intersectional Approach to Understanding Depression among Middle-Class Black Women. *Women Ther.* 2019;42(3-4):301-319.
22. Crowley Jack D. *Silencing the Self: Women and Depression.* Cambridge, MA. HUP; 1991.
23. Abrams JA, Hill A, Maxwell M. Underneath the Mask of the Strong Black Woman Schema: Disentangling Influences of Strength and Self-Silencing on Depressive Symptoms among U.S. Black Women. *Sex Roles.* 2019;80(9-10):517-526. PMC6510490
24. Black HK, White T, Hannum SM. The Lived Experience Of Depression In Elderly African American Women. *J Gerontol B Psychol Sci Soc Sci.* 2007;62(6):S392-398. PMC4539960
25. Hamm N. *PsychCentral*. African-American Women and Depression. 2016; *https://psychcentral.com/lib/african-american-women-and-depression#1*. Accessed March 25, 2021.
26. Walton QL, Shepard Payne J. Missing The Mark: Cultural Expressions Of Depressive Symptoms Among African-American Women And Men. *Soc Work Ment Health.* 2016;14(6):637-657.
27. Neal-Barnett A, Stadulis R, Murray M, Payne MR, Thomas A, Salley BB. Sister Circles as a Culturally Relevant Intervention for Anxious African American Women. *Clin Psychol (New York).* 2011;18(3):266-273. PMC3212099
28. Gaston MH, Porter GK, Thomas VG. Prime Time Sister Circles: Evaluating A Gender-Specific, Culturally Relevant Health Intervention To Decrease Major Risk Factors In Mid-Life African-American Women. *J Natl Med Assoc.* 2007;99(4):428-438. PMC2569659
29. Gilbert DJ, Goddard L. HIV Prevention Targeting African American Women: Theory, Objectives, And Outcomes From An African-Centered Behavior Change Perspective. *Fam Community Health.* 2007;30(1 Suppl):S109-111.
30. Skrine Jeffers K, Jones F, Mango J, et al. Being "In This Together" Is Central To Destigmatizing Depression Among African American Women: Findings From The Talk-Backs Of A Research-Based Play: Unpublished work. (2021).
31. World Health Organization. Depression. (2020). *https://www.who.int/news-room/fact-sheets/detail/depression*. Accessed March 25, 2021.
32. Greenberg PE, Fournier AA, Sisitsky T, Pike CT, Kessler RC. The Economic Burden Of Adults With Major Depressive Disorder In The United States (2005 And 2010). *J Clin Psychiatry.* 2015;76(2):155-162.
33. Holden KB, Bradford LD, Hall SP, Belton AS. Prevalence And Correlates Of Depressive Symptoms And Resiliency Among African American Women In A Community-Based Primary Health Care Center. *J Health Care Poor Underserved.* 2013;24(4 Suppl):79-93. PMC4020280
34. Office of the Surgeon General, National Institute of Mental Health. Mental Health: Culture, Race, and Ethnicity: A Supplement to Mental Health: A Report of the Surgeon General. (2001). *https://www.ncbi.nlm.nih.gov/books/NBK44243*. Accessed March 25, 2021.
35. Bailey RK, Mokonogho J, Kumar A. Racial And Ethnic Differences In Depression: Current Perspectives. *Neuropsychiatr Dis Treat.* 2019;15:603-609. PMC6390869
36. Keyes CL. Promoting And Protecting Mental Health As Flourishing: A Complementary Strategy For Improving National Mental Health. *Am Psychol.* 2007;62(2):95-108.
37. Beauboeuf-Lafontant T. You Have to Show Strength:An Exploration of Gender, Race, and Depression. *Gender & Society.* 2007;21(1):28-51.
38. Watson-Singleton NN. Strong Black Woman Schema And Psychological Distress: The Mediating Role Of Perceived Emotional Support. *J Black Psychol.* 2017;43(8):778-788.
39. Jones C, Shorter-Gooden K. *Shifting: The Double Lives of Black Women in America.* New York City: Harper Collins; 2003.

40. Woods-Giscombé CL. Superwoman Schema: African American Women's Views On Stress, Strength, And Health. *Qual Health Res.* 2010;20(5):668-683. PMC3072704
41. Wersebe H, Lieb R, Meyer AH, Hofer P, Gloster AT. The Link Between Stress, Well-Being, And Psychological Flexibility During An Acceptance And Commitment Therapy Self-Help Intervention. *Int J Clin Health Psychol.* 2018;18(1):60-68.
42. Tavakoli N, Broyles A, Reid EK, Sandoval JR, Correa-Fernández V. Psychological Inflexibility As It Relates To Stress, Worry, Generalized Anxiety, And Somatization In An Ethnically Diverse Sample Of College Students. *J Contextual Behav Science.* 2019;11:1-5.
43. Hayes SC, Strosahl KD, Wilson KG. *Acceptance And Commitment Therapy: An Experiential Approach To Behavior Change.* New York City: Guilford Press; 1999.
44. Samaan M, Diefenbacher A, Schade C, et al. A Clinical Effectiveness Trial Comparing ACT And CBT For Inpatients With Depressive And Mixed Mental Disorders. *Psychotherapy Res.* 2021;31(3):372-385.
45. Thomas VG, Gaston MH, Porter GK, Anderson A. Prime Time Sister Circles(®)II: Evaluating a Culturally Relevant Intervention to Decrease Psychological and Physical Risk Factors for Chronic Disease in Mid-Life African American Women. *J Natl Med Assoc.* 2016;108(1):6-18.
46. Taylor S. *Affiliation And Stress.* New York City: Oxford University Press; 2014.
47. Chinn J, Martin I, Redmond N. Health Equity Among Black Women in the United States. *J Womens Health (Larchmt).* 2021;30(2):212-219.
48. Stuckey HL, Nobel J. The Connection Between Art, Healing, and Public Health: A Review of Current Literature. *Am J Public Health.* 2010;100(2):254-263.
49. Jensen A, Bonde L. The Use Of Arts Interventions For Mental Health And Wellbeing In Health Settings. *Perspectives in Public Health.* 2018;138(4):209-214.
50. Field W, Kruger C. The Effect of an Art Psychotherapy Intervention on Levels of Depression and Health Locus of Control Orientations Experienced by Black Women Living with HIV. *S Afr J Psychol.* 2008;38(3):467-478.
51. Neal-Barnett AM, Stadulis R, Payne MR, et al. In The Company Of My Sisters: Sister Circles As An Anxiety Intervention For Professional African American Women. *J Affect Disord.* 2011;129(1-3):213-218. PMC3022958
52. Miranda J, Woo S, Lagomasino I, Hepner K, Wiseman S, Munoz R. Group Leader's Introduction: Group Cognitive Behavioral Therapy for Depression. (2006). *https://i4health.paloaltou.edu/manuals/bright-manuals.html*. Accessed March 25, 2021.
53. Sherbourne CD, Meredith LS, Rogers W, Ware JE. Social Support And Stressful Life Events: Age Differences In Their Effects On Health-Related Quality Of Life Among The Chronically Ill. *Qual Life Res.* 1992;1(4):235-246.
54. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: Validity Of A Brief Depression Severity Measure. *J Gen Intern Med.* 2001;16(9):606-613. PMC1495268
55. Sekhon M, Cartwright M, Francis JJ. Acceptability Of Healthcare Interventions: An Overview Of Reviews And Development Of A Theoretical Framework. *BMC Health Serv Res.* 2017;17(1):88.
56. Cohen S, Kamarck T, Mermelstein R. A Global Measure Of Perceived Stress. *J Health Social Behav.* 1983;24(4):385-396.
57. Watson D, Clark LA, Tellegen A. Development and validation of brief measures of positive and negative affect: The PANAS scales. *J Pers Soc Psychol.* 1988;54(6):1063-1070.
58. Merz EL, Malcarne VL, Roesch SC, et al. Psychometric properties of Positive and Negative Affect Schedule (PANAS) original and short forms in an African American community sample. *J Affect Disord.* 2013;151(3):942-949. PMC3934411

59. Bond FW, Hayes SC, Baer RA, et al. Preliminary Psychometric Properties Of The Acceptance And Action Questionnaire-II: A Revised Measure Of Psychological Inflexibility And Experiential Avoidance. *Behav Ther.* 2011;42(4):676-688.
60. Moin T, Duru OK, Turk N, et al. Effectiveness of Shared Decision-making for Diabetes Prevention: 12-Month Results from the Prediabetes Informed Decision and Education (PRIDE) Trial. *J Gen Intern Med.* 2019;34(11):2652-2659. PMC6848409
61. Castellon-Lopez Y, Skrine Jeffers K, Duru OK, et al. Psychometric Properties of the Altarum Consumer Engagement (ACE) Measure of Activation in Patients with Prediabetes. *J Gen Intern Med.* 2020;35(11):3159-3165. PMC7661602
62. Skrine Jeffers K, Castellon-Lopez Y, Grotts J, et al. Diabetes Prevention Program attendance is associated with improved patient activation: Results from the Prediabetes Informed Decisions and Education (PRIDE) study. *Prev Med Rep.* 2019;16:100961. PMC6732720

Evaluating the Feasibility and Acceptability of a Therapeutically-grounded Virtual Sister Circle for Black Women with Depressive Symptoms

Protocol Number: UCLA IRB #21-001322 (approved 10/20/21)

National Clinical Trial (NCT) Identified Number: NCT04837573

Principal Investigator*: Kia Skrine Jeffers, PhD, RN, PHN

Grant Title: UCLA Resource Center for Minority Aging Research / Center for Health Improvement of Minority Elderly (RCMAR/CHIME)

Grant Number*: P30AG021684 and UL1TR001881

Funded by: NIA and NCATS

Version Number: Not applicable

1 July 2022

Tools Saved at 12:44 PM Published Preview Publish

WSYS Sister Circle Study - Informed Consent

iQ Score: Great

Informed Consent

INTRODUCTION
Kia Skrine Jeffers, PhD, RN, PHN, from the School of Nursing at the University of California, Los Angeles (UCLA) is leading a research study. This study is being funded by the Resource Center for Minority Aging Research (RCMAR) via the National Institutes of Health/National Institute on Aging. You were selected as a possible participant in this study because you self-identify as a Black/ African American women who has had more stress or negative emotions lately and you want to live a more fulfilling life. Your participation in this research study is voluntary.

WHAT SHOULD I KNOW ABOUT A RESEARCH STUDY?
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide. W

WHY IS THIS RESEARCH BEING DONE?
This study is being done to see if Black women think a 6-session, virtual sister circle protocol that centers Black women is feasible and useful for women like them who want to live their best lives.

HOW LONG WILL THE RESEARCH LAST AND WHAT WILL I NEED TO DO?
Participation will take a total of about 2 hours per session for 6 sessions (approximately 12 hours total). If you volunteer to participate in this study, the researcher will ask you to do the following:
- Attend 6 weekly Sister Circle sessions via Zoom with other Black women.
- Complete surveys at three timepoints. The surveys will ask you about your stress, emotions and thought processes.
- Participate in a focus group to give your feedback on the Sister Circle experience.

Protocol ID:IRB#21-001322 UCLA IRB Approved Approval Date: 10/20/2021 Through: 10/11/2022 Committee: South General IRB

ARE THERE ANY RISKS IF I PARTICIPATE?
The potential risks to study participants include experiencing prolonged or heightened depressive symptoms (e.g., feelings of sadness or hopelessness).

ARE THERE ANY BENEFITS IF I PARTICIPATE?
You may benefit from the study by experiencing a reduction of stress, feeling as though you're living a more purposeful life, and feeling a sense of support among a community of Black women who understand you. The results of the research may benefit society in terms of our collective ability to address stress, negative emotions, and other depressive symptoms in community settings.

WHAT OTHER CHOICES DO I HAVE IF I CHOOSE NOT TO PARTICIPATE?
Your alternative to participating in this research study is to not participate.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?
The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security.

All participants will be asked to keep what is said during the group discussion between the participants only. However, complete confidentiality cannot be guaranteed.

USE OF PERSONAL INFORMATION THAT CAN IDENTIFY YOU:
A code will be used to identify you and your research data. The codebook that links the code to your personal information will be stored in an encrypted file in the PI's secure, UCLA Box (storage system).

HOW INFORMATION ABOUT YOU WILL BE STORED:
All study data will be stored in the PI's secure, UCLA Box. Your personal identifiers will be destroyed when the study ends.

PEOPLE AND AGENCIES THAT WILL HAVE ACCESS TO YOUR INFORMATION:
The research team and authorized UCLA personnel may have access to study data and records to monitor the study. Research records provided to authorized, non-UCLA personnel will not contain identifiable information about you. Publications and/or presentations that result from this study will not identify you by name.

Employees of the University may have access to identifiable information as part of routine processing of your information, such as processing payment. However, University employees are bound by strict rules of confidentiality.

HOW LONG INFORMATION FROM THE STUDY WILL BE KEPT:
Data containing identifiable information will be destroyed at the end of the study.

USE OF DATA FOR FUTURE RESEARCH Your de-identified data may be kept for use in future research

WILL I BE PAID FOR MY PARTICIPATION? You will receive a $20 Amazon e-gift card for each of the six virtual Sister Circle sessions that you attend and $10 gift cards for completing baseline and follow-up surveys (up to $140 value). The e-gift cards will be emailed to you within 3 business days of the session that you attend.

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?
The research team:
If you have any questions, comments or concerns about the research, you can talk to the one of the researchers. Please contact:
Dr. Kia Skrine Jeffers, Principal Investigator
VirtualSisterCircleStudy@gmail.com
(424) 272-5909

UCLA Office of the Human Research Protection Program (OHRPP):
If you have questions about your rights as a research subject, or you have concerns or suggestions and you want to talk to someone other than the researchers, you may contact the UCLA OHRPP by phone: (310) 206-2040; by email: participants@research.ucla.edu or by mail: Box 951406, Los Angeles, CA 90095-1406.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?
• You can choose whether or not you want to be in this study, and you may withdraw your consent and discontinue participation at any time.
• Whatever decision you make, there will be no penalty to you, and no loss of benefits to which you were otherwise entitled.
• You may refuse to answer any questions that you do not want to answer and still remain in the study.

By clicking the button below, you acknowledge: Your participation in the study is voluntary. You are at least 18 years of age. You are aware that you may choose to terminate your participation at any time for any reason. Information about this study is posted on ClinicalTrials.gov.

- ○ I consent to participate in the study.
- ○ I do not consent, I do not wish to participate.

Import from library | Add new question

Add Block

End of Survey

We thank you for your time spent taking this survey.

Your response has been recorded.