MANUAL OF PROCEDURES (MOP)

Adapting the SHARE for Dementia Early-Stage Dyadic Intervention: A Stage I Pilot Study with African American Families

1P30AG086562-01

(Version 1.0)

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1.0 STUDY OVERVIEW

Study Title: Adapting the SHARE for Dementia Early-Stage Dyadic Intervention: A Stage I Pilot Study with African American Families

This pilot project is funded as part of the Roybal Centers, by the National Institute on Aging (NIA). The project involves culturally tailoring the SHARE program for Black/African American PLWDs and their CGs in the early to moderate stages of dementia. The goal of this study is to support conversations around care values and preferences in Black/African American dyads living with a dementia diagnosis in an effort to address disparities.

This two-year study is divided into Stage 1A and Stage 1B, involving four main aims:

Stage 1A; Culturally tailor SHARE for African American dyads

Aim 1: Review SHARE for Dementia materials with an Advisory Committee (AC; 6-10 African Americans with lived experience and experts) to identify distinct needs of African American care dyads and culturally adapt SHARE using this input. Deliverables: Develop SHARE V1 Culturally tailored V1 SHARE Counselor Manual, V1 SHARE Guide for Families, and V1 SHARE Counselor training

Aim 2: Conduct focus groups with African American care dyads (n=2 groups; n=10 dyads total, or until saturation) and community service provider staff (n= 2 groups; n=10, or until saturation) to identify strengths and limitations of the V1 SHARE materials, procedures, and protocols. Deliverables: SHARE for African Americans (Version 2;V2); Culturally tailored V2 SHARE Counselor Manual, V2 SHARE Guide for Families, and V2 SHARE Counselor training

Stage 1B; Conduct a pilot RCT of the adapted SHARE versus usual care

Aim 3: Train SHARE counselors (n=20) to implement V2 of SHARE.

Aim 4: Examine: a) the acceptability and feasibility and; 2) preliminary efficacy of the culturally adapted V2 of SHARE in a fully powered trial with 120 African American care dyads.

2.0 STUDY ORGANIZATION AND RESPONSIBILITIES

Table 1: Staff Roster

Name	Address	Phone	Email	Role	Responsibilities
Silvia Orsulic-Jeras, MA	*Benjamin Rose Institute on Aging 11890 Fairhill Rd. Cleveland, OH 44120*	(216) 373-1625	sjeras@benrose.org	PI	Overall study management, clinical trial oversight, staff supervision, humans subjects protections
Lacey DiFranco, MA	*Benjamin Rose Institute on Aging 11890 Fairhill Rd. Cleveland, OH 44120*	(216) 373-1722	ldifranco@benrose.org		
Zoe Fete, MS	*Benjamin Rose Institute on Aging 11890 Fairhill Rd. Cleveland, OH 44120*	(216) 373-1929	zfete@benrose.org	Project Coordinator	Data management and field operations
Donna Salaam, MA	*Benjamin Rose Institute on Aging 11890 Fairhill Rd. Cleveland, OH 44120*	(216) 373-1747	dsalaam@benrose.org	Research Assistant	Recruitment and screening
Sarah Nicolay	*Benjamin Rose Institute on Aging 11890 Fairhill Rd. Cleveland, OH 44120*	(216) 373-1738	snicolay@benrose.org		
Kelsey Minter	*Benjamin Rose Institute on Aging 11890 Fairhill Rd. Cleveland, OH 44120*	(216) 373-1617	kminter@benrose.org		
Talea Cornelius, PhD, MSW	*Columbia University 630 West 168th Street New York, NY 10032*		tmc2184@cumc.columbia.edu	Consultant	Statistical analysis
Kalisha Bonds Johnson, PhD	Emory University 57 Executive Park S	(404) 727-5937	Kalisha.bonds@emory.edu	Consultant	Focus group, advisory council,

	Suite 190, Rm 132 Atlanta, GA 30329				and clinical trials recruitment
Lauren Parker, PhD	Johns Hopkins University 624 N. Broadway Hampton House 904 Baltimore, MD 21205		lparke27@jhu.edu	Consultant	Assist with intervention adaptation and ongoing counselor supervision

3.0 STUDY FLOW

REFERRALS AND SCREENING

Referral from Counselor
- Fill out *Contact Release Form* once family agrees to be contacted by Benjamin Rose
-**Email** completed release form to SHARE4AA@benrose.org

Referral from Benjamin Rose
- Minimally required info: CG/CR name, phone number, email, referral source, and best times to contact

Pre-screening
- In REDCap, DONNA: 1) Inputs contact info in REDCap; 2) Conducts pre-screener; 3) Collects demographics. If failed pre-screen, use end call script. Dyad is entered into the Screening Failure report for CROMS. If passed, dyad proceeds to formal SCREENING in REDCap.

Screening
- DONNA will first administer the Dementia Rating Scale and full screen to CG to determine eligibility; then will administer full screen to PWD.
- If eligible, DONNA will record this at the end of screener in REDCap and invite dyad to participate.
- If dyad agrees to participate, DONNA will notify ZOE by email with subject heading DYADID Ready for Interview Assignment. Record is enrolled in CROMS.
- If dyad is not eligible or refuses to participate, dyad will be entered into the Screening Failure report in CROMS.

INTERVIEWS

Interviewer is assigned
- ZOE prepares assignment sheet; ZOE informs DONNA of interviewer; DONNA sends enrollment packet and records sent in REDCap
- ZOE sends 1 email to Interviewer with ID# in subject line
- ZOE sends 2nd email with assignment sheet with QR code

Interviewer schedules T1
- INTERVIEWER schedules T1 with dyad within 48 hours
- INTERVIEWER notifies ZOE of date/time by email
- ZOE adds date/time of interview in ***Interviewer Tracking Sheet***

Interviewer conducts T1
- INTERVIEWER completes Time 1 (baseline) with each care partner over the phone and enters data using MyCap
-INTERVIEWER emails Zoe with updated assignment sheet

T1 completed
- ZOE conducts data check in REDCap within 24 hours and resolves any errors with INTERVIEWER
- ZOE emails LACEY & KELSEY that dyad is ready to be assigned to Counselor; KELSEY fills out *initial care values comparison, PWD's Initial Care Circles, and CG Initial Care Circles* and uploads to Teams Channel once LACEY creates assignment sheet.

Time 2 Control Assignment/Completion
- ZOE assigns INTERVIEWER for T2 using same protocols as T1
- INTERVIEWER schedules T2 with dyad within 48 hours
- INTERVIEWER notifies Zoe of completion; ZOE conducts data check in REDCap within 24 hours and resolves any errors with INTERVIEWER
- ZOE records T2 completion in ***Interview Tracking*** Sheet and REDCap

Time 2 Treatment Assignment/Completion
- ZOE assigns INTERVIEWER for T2
- INTERVIEWER schedules T2 with dyad within 48 hours
- INTERVIEWER notifies Zoe of completion; ZOE conducts data check in REDCap within 24 hours and resolves any errors with INTERVIEWER
- ZOE records T2 completion in REDCap

TREATMENT/CONTROL SESSIONS

Counselor is assigned [using SHARE4AA@benrose.org]
- LACEY sends 1 email to COUNSELOR:
1. Only ID# in subject heading; instructs COUNSELOR to check their Teams Channel
2. Teams Channel will contain the following prefilled forms: *assignment sheet (all); initial electronic case file (all);* ***TX only****: initial care values comparison; initial SHARE Care Circles for PWD preferences/CG perceptions; SHARE Care Circles Exercise*

Counselor schedules Session 1/Control Session
- COUNSELOR will first notify dyad if they will be receiving one or up to six sessions
- COUNSELOR schedules Session 1/Control Session with dyad within 48 hours and notifies LACEY of date/time; LACEY notes ***Counselor Tracking Sheet***
- If unable to contact dyad after 2 weeks, COUNSELOR notifies LACEY who will continue to attempt to contact the dyad
- Dyad will be marked as ***dropped out of study*** if are unable to be reached within 4 weeks of assignment date

Session 1 Treatment/Control Session Completed
- At the end of Session 1/Control session, COUNSELOR uploads the Electronic Case File and other required data into TEAMS Channel
-If Control, COUNSELOR notifies LACEY of completion of case
-LACEY assigns post-session evaluation to KELSEY to complete within 48 hours; -KELSEY notifies LACEY dyad evaluation is complete
-LACEY notifies ZOE when Control case is ready for Time 2

Counselor schedules Sessions 2 - 5
- At the end of each session, COUNSELOR schedules and completes remaining sessions
- At the end of each session, COUNSELOR uploads the completed Electronic Case File and other required data into their TEAMS Channel
-LACEY notes date/time of next session into ***Counselor Tracking Sheet*** and manages case file/evaluation data entry

After Session 5
-COUNSELOR notifies LACEY of treatment case completion
-LACEY notes completion in ***Counselor Tracking Sheet*** & REDCap

PAYMENT AND FOLLOW-UP

Control Group Case is Complete
- SARAH processes subject payment and sends thank you letter

Treatment Group Case is Complete
- SARAH processes subject payment and sends thank you letter

4.0 INFORMED CONSENT

During the screening phone call, researchers will explain the study and consent process and ask the respondent to verbally consent after reading the consent form. If a participant does not consent, they will not be enrolled. All consent forms will include the following information in clear and understandable language: (1) participants agree in an entirely voluntary manner to participate in the specific research project, the purpose of which is stated, as well as the anticipated sources (i.e., questionnaires), use, and benefits of the data; and (2) participants understand that they are free to decline to participate or to withdraw their participation at any time; (3) participants understand that their participation or refusal in this research project in no way affects the availability or quality of health and social services that they are currently receiving or might wish to receive in the future; and (4) participants understand that all information in the research project will be kept confidential according to strict procedures and that results will be reported in an aggregate manner. At each phase of the consent process, users, staff, and persons with dementia will be informed of the voluntary nature of their participation. Once consented, a physical copy of the verbal consent will be sent to all participants for their records as part of the enrollment packet.

4.1 HIPAA Authorization

The Research Screener will explain to the dyad that the research team will collect the PWD's protected health information (PHI) for use in this study, as specified in the consent form they have signed. Participant information will only be accessed as needed to collect study-relevant data, including the following: diagnoses, medications, pertinent health history, demographics, such as age, race/ethnicity, date of birth, sex, and education level.

5.0 RECRUITMENT AND RETENTION

5.1 Participant Recruitment

Our plan is to recruit 120 Black and African American dementia dyads. The Benjamin Rose Institute on Aging in Cleveland, OH will serve as the primary recruitment site. We will recruit locally in Cleveland, OH and surrounding areas through Benjamin Rose Institute on Aging's Rose Centers for Aging Well, which houses our home delivered meals program; our Empower and Strengthening Ohio's People financial counselor program, our Eldercare Services Institute that offers social work and mental health services, and our Margaret Wagner Apartment buildings. We will also utilize Benjamin Rose's multitude of community connections through local churches, various community-based agencies, and large healthcare systems. The National Caucus and Center for Black Aging, Inc. (NCBA) will also serve as a recruitment site for the clinical trial. NCBA is the preeminent national organization on issues impacting minority citizens aged 55 and older. The Cleveland chapter is located in the Fairhill Center for Aging and houses the Senior Community Service Employment Program (SCSEP), a paid community service and work-based training program that serves a large percentage of AA families (see letters of support).

Project Consultant, Dr. Bonds Johnson, will assist in recruiting dyads through Emory University Goizueta Alzheimer's Disease Research Center Minority Engagement Core and Emory Healthcare Integrated Memory Care Clinic. Using the church connections of the Emory University Goizueta Alzheimer's Disease Research Center Minority Engagement Core and Georgia State University Dementia Friendly Faith Village Community Program, we will advertise in church bulletins. Church leaders and congregation members may also refer a dyad who may be

interested in the study. Through the Emory Healthcare Integrated Memory Care Clinic, we will work with clinicians to identify potentially eligible participants. In addition to the local recruitment, we will use discussion boards of national organizations (American Psychiatric Nurses Association and Gerontological Society of America) and community connections of social and professional organizations (Zeta Phi Beta Sorority, Incorporated). The members of these organizations can also refer dyads who may be interested in the study. If additional dementia dyads are needed, we will use snowball recruitment, asking enrolled caregivers to refer other dementia dyads like themselves to participate.

Enrollment packets will be mailed to eligible and enrolled care dyad participants individually. Included in each care partner's enrollment packet will be a cover letter, a study flyer, two copies of the verbal consent form (to be retained for the person's records), and a Microsoft Teams instructional guide to prepare for remote sessions. The cover letter, consent form, and flyer will have phone numbers, addresses, and email addresses for the PI and the designated IRB. The person will be invited to contact any of these individuals if they have any questions. The consent form will include detailed information about what participation in the study entails for residents. It will also list all of the potential risks of the study and ways in which researchers will be protecting against the risks. Potential benefits will also be described. In all recruitment materials, it will be made clear that participation in this study is voluntary, and that participants can stop participating at any time.

Recruitment will continue until we reach the target sample size (N=120 dyads) for Aim 4. If the recruitment strategies do not obtain the desired sample, we will use social media (e.g., Facebook, twitter). We will also post/distribute flyers describing the study and contact information in private geriatrician offices, senior centers, libraries, and other public venues so that caregivers can contact the study office for further information and enrollment.

Recruit dementia care professionals to be trained in V2 of the adapted SHARE (i.e., adapted for African American dyads). Direct service staff from various community-based service organizations or clinic-based settings will be trained to conduct SHARE (n=20). The benefit of working with a broad group of providers is that they will have varying levels of prior training and experience working with African American families. We anticipate that few staff will be trained specifically in dementia-related issues that emphasize working with care dyads. Each trainee will be asked to complete the SHARE online training course within a two week-long period of time. Three additional hour-long webinars will be presented to SHARE Counselor trainees that will be focused on the specific cultural adaptations determined by the Advisory Council and Focus Groups in the Stage 1A study.

5.2 Participant Retention

Missing data and attrition are expected. We conservatively estimated missing data of 10% of the entire sample and potential attrition of 20%. Thus, we are recruiting 120 dementia dyads for Aim 4 to yield a minimum final sample of around 100 AA dementia dyads. To promote retention between data collections, we will send "thank you" notes, birthday cards, and holiday greetings. Members of the research team will establish a positive rapport and good working relationships with participants to reinforce participation throughout the study period. In addition, participants will receive a $25 honorarium for participating in data collection in each data point (baseline and follow-up).

6.0 SCREENING AND ELIGIBILITY CRITERIA

6.1 Screening

1. Pre-Screening will begin over the telephone with a Research Screener contacting the care partner that was referred. The Research Screener will ask a series of questions to determine if basic eligibility criteria are met:
    a. One or both care partners identify as non-Latinx Black or African American
    b. One care partner reports signs and symptoms of mild to moderate dementia memory concerns (e.g., Alzheimer's disease, vascular dementia, mild cognitive impairment, etc.) and one care partner identifies with being the person who is or will provide assistance to them in the future
    c. Both care partners live in the community (e.g., home or apartment) and not in an institutionalized setting (e.g., assisted living or nursing home)
    d. At least one care partner has a computer and a wifi connection they can use to participate in the study

    Once the dyad is pre-screened for eligibility:

2. Full screening is conducted by the Research Screener to make a final eligibility determination whether the PWD and CG meet the following inclusion / exclusion criteria:
    a. PWD is 50+ and CG is 18+
    b. Both care partners able to read and speak English
    c. PWD is diagnosed with dementia (of any type) or has symptoms consistent with mild to moderate dementia through CG report on the Dementia Severity Rating Scale.
    d. Neither care partner has a terminal illness diagnosis and is receiving hospice care

3. The Montreal Cognitive Assessment (MoCA) will be conducted by the Research Screener by interviewing the PWD.
    a. Eligibility will be determined by the DRS; the MoCA will be administered to the PWD during screening if the dyad screens in based on DRS results

6.2 Screening Log

After completing the screening process, the Research Screener will enter data into the Screening Log. The Screening Log will be digital in nature (an Excel spreadsheet) include the following information: the dyad's initials, identification number (screening number), age, gender, race, ethnicity, screening date, and eligibility status. (e.g., eligible for study participation and date enrolled; ineligible for study participation and reason; refused consent and reason). The file will be saved on the Benjamin Rose servers. Enrollment and screen failure data will be added into the respective CROMS databases.

6.3 Eligibility Criteria

Inclusion Criteria

PWD

PWD must reside in a community setting, such as a home or apartment, be 50+ years old, diagnosed with any type of dementia or report symptoms consistent with dementia, speak and read English.

CG

CG must identify as non-Latinx Black or African American or be caring for someone who is non-Latinx Black or African American, be at least 18 years old, speak and read English, and is a person who will have responsibility for helping with the PWD's care.

Exclusion Criteria

Dyad will be excluded if one or both care partners refuse to participate, either are bed confined, unable to communicate verbally, have serious visual or hearing impairments and if the PWD scores below moderate on the Dementia Severity Rating Scale as reported by the CG.

7.0 STUDY INTERVENTION

A total of 120 dyads will participate in the intervention. A Randomized Control Trial (RCT) will be conducted (with 60 in the control group and 60 in the treatment group).

The study will follow Barrera's Stages of Cultural Adaptation: 1. Information Gathering, 2. Preliminary Adaptation Design, 3. Preliminary Adaptation Test 4. Adaptation Refinement, 5. Cultural Adaptation Trial. See Figure 1. Below for an outline of how this model fits in with Stage 1A and Stage 1B.

The Stress Process Model (SPM) will also be applied. The revised domains of the SPM will incorporate: 1) Background Characteristics, 2) Primary Objective Stressors, 3) Targeted mechanisms of behavior change after receiving the adapted SHARE intervention, 4) Primary and Secondary Subjective Stressors, and 5) Psychosocial Well-Being Outcomes. See Figure 2. Below for an Overview of how these domains tie into the study and anticipated results.

Figure 1. Barrera's Stages of Cultural Adaptation

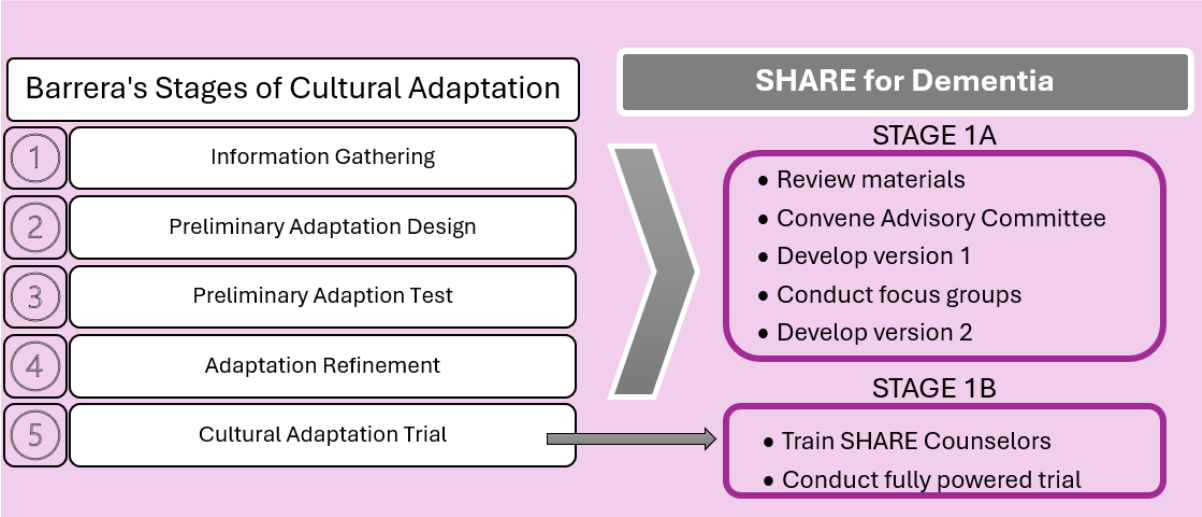
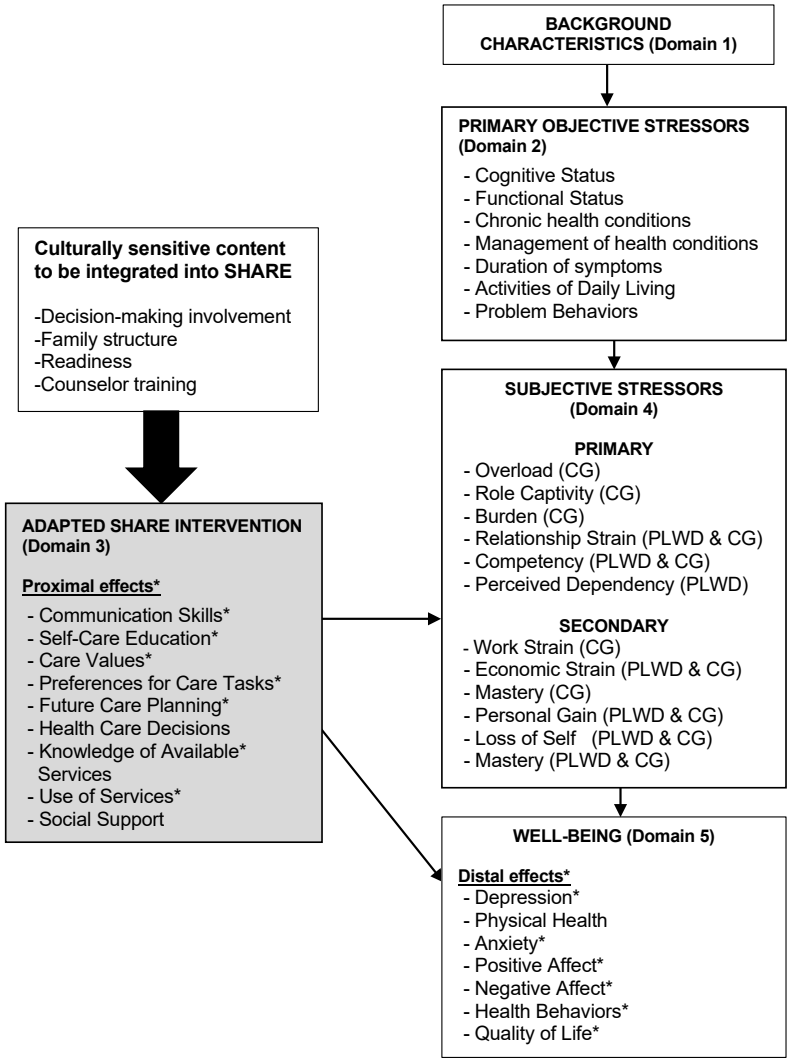


Figure 2. Stress Process Model



8.0 STUDY MEASUREMENTS AND PROCEDURES

See section 3.0 Study Flow for details on study procedures between screening and study completion. The below tables document the study timeline and schedule divided between PWD and CG study protocols.

PWD Timeline and Schedule				
Interview/Data Collection	**Screening (1 week)**	**Baseline (within 2 weeks after screening)**	**Treatment or Control Period (Tx; 8-10 weeks; C: single session)**	**Follow-Up (within 2 weeks of completion of intervention period)**
Informed Consent Form	**X**			
Confirm Age 50+ (Screening)	**X**			

Confirm Read & Speak English (Screening)	X			
Confirm Dementia Symptoms or Diagnosis (Montreal Cognitive Assessment; MOCA)	X			
Confirm Exclusion Criteria Do Not Apply	X			
Enrollment (if eligible)	X			
Service Availability Measure (SAM)		X		X
Care Values Scale		X		X
Preferences for Care Tasks Scale		X		X
Dyadic Relationship Scale (DRS)		X		X
Personal and Instrumental Activities of Daily Living (PADL & IADL)		X		X
Emotional-Intimacy Disruptive Behavior Scale (EIDBS)		X		X
Dementia Quality of Life +/- Affect		X		X
Center for Epidemiological Studies Depression Scale (CES-D)		X		X
Leisure & Healthy Behaviors		X		X
Quality of Life – AD (QoL-AD)		X		X
SHARE Care Plan (Treatment ONLY)			X	
Resource List (Control ONLY)			X	
Post-Session Evaluation (1 – Control; up to 6 – Treatment)			X	
Treatment Fidelity / Acceptability Measures			X	
Satisfaction Questions				X

CG Timeline and Schedule				
Interview/Data Collection	**Screening (1 week)**	**Baseline (within 2 weeks after screening)**	**Treatment or Control Period (Tx; 8-10 weeks; C: single session)**	**Follow-Up (within 2 weeks of completion of intervention period)**
Informed Consent Form	X			
Confirm Age 50+	X			

(Screening)				
Confirm Read & Speak English (Screening)	**X**			
Confirm Dementia Symptoms or Diagnosis (Dementia Rating Scale)	**X**			
Confirm Exclusion Criteria Do Not Apply	**X**			
Enrollment (if eligible)	**X**			
Service Availability Measure (SAM)		**X**		**X**
Care Values Scale		**X**		**X**
Preferences for Care Tasks Scale		**X**		**X**
Dyadic Relationship Scale (DRS)		**X**		**X**
Personal and Instrumental Activities of Daily Living (PADL & IADL)		**X**		**X**
Personal and Instrumental Activities of Daily Living (PADL & IADL)		**X**		**X**
Emotional-Intimacy Disruptive Behavior Scale (EIDBS)		**X**		**X**
Dementia Quality of Life +/- Affect		**X**		**X**
Center for Epidemiological Studies Depression Scale (CES-D)		**X**		**X**
Stress in Providing Care		**X**		**X**
Leisure & Healthy Behaviors		**X**		**X**
Quality of Life – AD (QoL-AD)		**X**		**X**
SHARE Care Plan (Treatment ONLY)			**X**	
Resource List (Control ONLY)			**X**	
Post-Session Evaluation (1 – Control; up to 6 – Treatment)			**X**	
Treatment Fidelity / Acceptability Measures			**X**	
Satisfaction Questions				**X**

9.0 TIMELINE AND SCHEDULE

Project Activities	Year 1				Year 2			
	Project Quarter				Project Quarter			
A. Stage 1A	1	2	3	4	5	6	7	8
1. Prepare SHARE for Dementia materials for review [Aim 1a].								
2. Recruit Advisory Council members [Aim 1a].								
3. Convene Advisory Council [Aim 1a].								
4. Adapt SHARE based on AC feedback [Aim 1b].								
5. Recruit sites/subjects for focus groups [Aim 2].								
6. Convene focus groups [Aim 2].								
7. Analyze focus group data [Aim 2].								
8. Revise SHARE and prepare Version 2 for testing [Aim 2].								
B. Stage 1B								
1. Recruit SHARE Counselors to be trained [Aim 3].								
2. Conduct SHARE Counselors Training (n=20) [Aim 3].								
3. Conduct clinical trial (n=120 African American dyads; 60 treatment/60 control) [Aim 4].								
4. Analyze results [Aim 4].								
5. Prepare final report & continue dissemination activities [Aim 4].								

SHARE COUNSELOR PROCEDURES

The Basics

SHARE Training Webinar

The goal of this training webinar is to familiarize SHARE Counselors with the SHARE for African Americans study and procedures related to recruitment and referral, enrollment, assignment, scheduling, and data collection.

The following materials will be reviewed:

- Contact Release Form
- Billing and Invoicing
- SHARE Care Values Comparison Tool
- SHARE Care Circles
- SHARE Care Plan

Pre-Training Preparation and Initial Training Requirements:

Prior to this webinar, you will have received and completed the following:

- Introduction call on the project and counselor requirements
- SHARE Counselor Online Training Course
- Human Subjects Protection Training (required to work with research human subjects)

The completion of the training course online will have prepared you to fulfill the role of a SHARE Counselor. For this webinar, the SHARE team will not discuss session specifics but instead focus on putting knowledge of the program to practice through case scenarios.

Microsoft Teams

Personalized Teams Channel

- You will be invited to a private Microsoft Teams Channel by the SHARE Research Team. Only you and the research team will have secure, and privacy protected access to case information housed in this channel
- The channel will be named by your first and last name
- There will be multiple documents within the channel
    - Resources Folder: Will house blank documents and fillable forms
    - Case Assignment Folders: Your case folders will be organized here by ID#/Group Assignment and will contain all the relevant documents for each case
    - Data Submission Folder: Here is where you will upload your completed data files [See Data Collection Procedures below]

Remote Delivery

This is a virtual study with all sessions taking place on a computer or tablet. You and your care partners may choose to use a desktop, laptop, or tablet to participate in sessions.

- SHARE Counselors will use Microsoft Teams to deliver SHARE Treatment and Control sessions with families
- Utilize Teams to create meeting links you will share with your care partners to log into the session
- SHARE Counselors can provide basic technology support to families trying to log in for sessions. Encourage care partners to seek help from other family or friends to help set up their computers/tablets to successfully participate
- If a family continues to struggle with technological aspects of the project, contact Donna at dsalaam@benrose.org for assistance.

CASE ASSIGNMENTS

Procedures

Case Assignment Procedures:

Research staff will assign screened and eligible care partners who have been through a baseline research interview to appropriate counselor based on logistics, such as geographic location, referral source, and counselor/family availability and date/time preferences.

- Zoe/Donna will send out **one** assignment email:
    1. Will have in the subject line: New Case Assignment: Case ####_Treatment/Control
    2. You will then go to your Microsoft Teams channel and locate the Assignment Info folder. Find the assignment sheet with the ID# from your assignment email.
    3. The assignment sheet will contain the family's contact information along with important details that the counselor needs to know in the notes section (i.e. best person/times to contact, diagnosis, ages of care partners if relevant, important information regarding availability or preferences that are known at the time, etc…).
    4. Within that case's folder in your Teams channel, you will also find the original electronic case file. When you first open that document, you will notice there will be some basic information populated for you. Once you begin your case, you will fill this out each time [**See Data Collection Procedures below**].

Referrals to the Program

- You are encouraged to refer potential families to the study. To do so, you would complete the **Consent to Contact Form** located in the Resourced folder in Teams Channel, and send to SHARE4AA@benrose.org. Donna will contact the family within a week and screen them for eligibility for the study.
- You may or may not be assigned your referred cases. These decisions will be made by the research team on a case-by-case basis.

CASE SCHEDULING

General Notes:

- Please **contact family within 48 hours of assignment** to schedule first (or only) session and immediately email **SHARE4AA@benrose.org** of scheduled session.
    - If session is not scheduled within 48 hours of assignment, please contact research staff at SHARE4AA@benrose.org to us know the status (haven't called yet, left a message, unable to contact, wrong number, etc…) and repeat every 48-hour interval until session is scheduled.
    - If you are not able to schedule the family within two weeks of assignment, the case will be turned back over to us. The SHARE team will discuss the next steps. Decisions will be made on a case-by-case basis and you will be informed of the status of the case once decisions are made.

- ***Treatment Group:*** Each subsequent session must be scheduled with the family at the end of a completed session - or- you may choose to schedule the entire program at once if that works for both counselor and family. When the SHARE Counselor completes their documentation within 48 hours of the completed session [**See Treatment Data Collection Procedures below**], the SHARE Counselor will have a space to list the date and time of the next scheduled session.

- ***Control Group:*** Upon completion of the control family's single session, the SHARE Counselor emails research staff letting them know of case completion at SHARE4AA@benrose.org. Upload the completed electronic case file within 48 hours of the completed session [**See Control Data Collection Procedures below**]. At this point, the SHARE Counselor is completed with this case.

DATA COLLECTION PROCEDURES

Treatment

General Notes:

All required data collection for the project will be described below with timelines, data sharing procedures, and contact information in case there are issues. For any data collection challenges, please contact Project Coordinator Zoe Fete – zfete@benrose.org or (216) 373-1929. For clinical guidance, adverse reactions, or concerns about subject safety, reach out to Principal Investigator, Silvia Orsulic-Jeras. For non-emergencies, email – sjeras@benrose.org -or- phone (216) 373-1625. For urgent matters, Silvia may be reached at (216) 570-8894.

All SHARE Program Counseling Data Collection Tools for Treatment Group Cases are listed below:

Post-Session Case Notes:

Electronic Case Files: Throughout your sessions, you are expected to take detailed notes in the electronic case file provided to you in your Microsoft Teams channel for each assigned case. You will upload the completed version into the Teams folder for each session within ***48 hours*** of completion. The electronic case file includes each of the following sections, per session:

- *Session Preparation*: A list of what tools you will need to have reviewed and/or ready prior to that session.
- *Changes Since Last Session*: Here you will report any major the changes that either care partner has experienced since the last time you spoke with/met them. This is an important reporting requirement to our funder. If anything, major has occurred, please fill out an **Adverse Event Form** as soon as possible and send it as an encrypted file to zfete@benrose.org within 24 hours -or- upload it to your Teams Channel.
- *Session Information*: Basic information about the session [date, time of session, session duration, PWD location, CG location).
- *Session Counselor Evaluation*: Each treatment session will include an evaluation of session components from your perspective.
- *Readiness Ratings*: You will rate each care partner's level of readiness at the end of each session and note any important contents to support your rating in the box provided.
- *Session Notes*: Complete notes on your session at the of the case file for that session.

Procedures:

- **Electronic Case File**: Save the document after each completed session and name the most recent case file into the Completed Data Folder for your case using the following convention:
  - ####_Session1_Case File Complete
  - ####_Session2_Case File Complete
  - ####_Session3_Case File Complete
  - ####_Session4_Case File Complete
  - ####_FamilySession_Case File Complete
  - ####_Session5_Case File Complete

  At the completion of all sessions, your case should have 5-6 completed case files (5 if there is no family session held).

  *You will **NEVER** share the Electronic Case File with the family. This is a research document **ONLY**.
- **Other Fillable Data Forms:**

  [You will email these to families using encryption as often as you'd like]
  - **Care Values**: We will provide an initial Care Values Comparison document in a Care Values folder for you in your Teams Channel for each case. You will use this document to conduct the Care Values Discussion in Session 1.
  - **SHARE Care Circles**: We will provide you with three SHARE Care Circles documents for you in a Care Circles folder in your Teams Channel for each case. Two files will be there for you: PWD's Care Circles and CG's Perceptions Care Circles. You will use then use the PWD's document to conduct the Care Preferences discussions in Session 2. You will resave that document into a new version that will contain the final Care Circles. You will name that document beginning with the ID#: ####_CareCircles_Session2_FINAL.

Data Collection Milestones:

At the end of each session, the following data elements are due in your Microsoft Teams Channel folder in the Completed Data folder within 48 hours of your session ending:

Session 1:

- Electronic Case file
- Revised Care Values file (if care values were adjusted in Session 1)

Session 2:

- Electronic Case file
- Revised Care Values file (if care values were adjusted in Session 2)
- Revised Care Circles file (demonstrating the new SHARE Care Circles)

Session 3:

- Electronic Case file
- Completed SHARE Care Plan created in Session 3
- Revised Care Values file (if care values were adjusted in Session 3)
- Revised Care Circles file (if care preferences were adjusted in Session 3)

Session 4:

- Electronic Case file
- Completed Family Session Agenda [Counselor Version; the Family version you will send to the family]
- Revised SHARE Care Plan (if Plan changed after having Session 4 discussions)
- Revised Care Values file (if care values were adjusted in Session 4)
- Revised Care Circles file (if care preferences were adjusted in Session 4)

Family Session:

- Electronic Case file
- Revised SHARE Care Plan (if Plan changed after Family Session)
- Revised Care Values file (if care values were adjusted in Family Session)
- Revised Care Circles file (if care preferences were adjusted in Family Session)

Session 5:

- Final Electronic Case file
- Final SHARE Care Plan (if Plan changed after Family Session)
- Final Care Values file (if care values were adjusted in Family Session)
- Final Care Circles file (if care preferences were adjusted in Family Session)

Post Session Email:

Once you are completed with your final session for a case, within 24 hours you will email SHARE4AA@benrose.org that your case is complete and all of your data have been collected.

Evaluations of Your Care Partners:

At the end of each session, a researcher will call the family on the phone and will ask them questions about their experiences. Please remind the family at the end of each session that someone from Benjamin Rose is going to call them to check in. This call with take place within 48 hours of your data being received in the Teams folder, confirming the session took place.

****This concludes your treatment case****

DATA COLLECTION PROCEDURES

Control

All SHARE Program Counseling Data Collection Tools for Control Group Cases are listed below:

Post-Session Case Notes:
Throughout your session, you are expected to take detailed notes in the control group electronic case provided to you in your Microsoft Teams channel for each assigned control case. You will upload the completed version into the Teams folder Completed Data for that case within ***48 hours*** of completion of the session, following these procedures.

Procedures:

- **Electronic Case File**: Save the document after your completed control group session into the Completed Data Folder for your case using the following convention:
  - ####_ControlSession_Case File Complete
- **Other Fillable Data Forms:**
  - **Control Group Handout**: We will provide the Control Group Handout in the Resources folder within a Control Group Materials subfolder in your Teams Channel for each case. You will use this blank document to conduct the Control Group session with your assigned control care partners.

Data Collection Milestones:
At the end of your control session, the following data elements are due in your Microsoft Teams Channel folder in the Completed Data folder within 48 hours of your session ending:

Session 1:

- Completed Control Group Electronic Case file
- Completed Control Group Handout

Post Session Email:

- Once you are completed with your control case, within 48 hours you will email SHARE4AA@benrose.org that your case is complete and all of your data have been collected.

Evaluations of Your Care Partners:

- At the end of your control session, a researcher will call the family on the phone and will ask them questions about their experience. Please remind the family at the end of the session that someone from Benjamin Rose is going to call them to check in. This call with take place within 48 hours within your data being received in the Teams folder, confirming the session took place.

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11.0 FOLLOW-UP

The intervention period in this low-risk study of a non-pharmacological intervention is just three months in length. As such, follow up is not required. The final point of contact for all dyads will be the post-treatment assessment / interview. Upon completion of the study, there will be no follow-up required.

12.0 EARLY DISCONTINUATION

Participants are free to withdraw from participation in the study at any time and for any reason.

13.0 SAFETY REPORTING

Ms. Orsulic-Jeras and Dr. Johnson (PI and Consultant) will be responsible for ensuring participants' safety on a daily basis during their participation in Aim 4. Data and safety monitoring will be assured by the study's Research Team Senior key personnel: The PI and study consultants, Dr. Bonds-Johnson and Dr. Cornelius, are experts in the field of dementia/chronic illness and dyadic research. Along with Ms. Orsulic-Jeras, they will make up the study's Data and Safety Monitoring Committee (DSMC). This team will act to monitor participant safety, evaluate the progress of the study, review procedures for maintaining the confidentiality of data, the quality of data collection, management, and analyses.

Ms. Orsulic-Jeras, Dr. Bonds-Johnson, and Dr. Cornelius will be informed of any serious adverse events as soon as they occur and will notify the Institutional Review Board of record within 24 hours of notification. The DSMC will meet quarterly with members of the research team either in-person or by teleconference to review the study's progress, review data quality, and participants' safety. At these meetings, an evaluation of the progress of the study will be reviewed, including periodic assessments of data quality, timeliness of recruitment, the appropriateness of the strategies for recruiting participants into the study, assessing the participants' risk in using SHARE materials, and other factors that might affect the study's outcomes.

In the event of an adverse reaction, the DSMC will meet within 24 hours and the following information will be reviewed:

- Participant's study status
- How the participant was recruited into the study and the efforts that took place to retain him/her.
- The nature of the adverse reaction and a determination of how the participant's safety has been threatened as a result.
- A recommendation for how to treat the adverse reaction. In most cases, a recommendation would be to discontinue the individual's participation in the intervention and/or to withdraw the participant from the study. In more severe cases, the participant might be referred to an identified expert (the Alzheimer's Association, a geriatric care manager or licensed clinical social worker, etc.).
- If the adverse reaction is deemed to be very serious (i.e., suicidal risk or the health/well-being of the participant is in jeopardy), the case will be reported to the appropriate authorities to intervene on the situation immediately.
- Any significant adverse reactions will be reported to the IRB within 24 hours of notification.

For the purposes of this study, a participant is considered enrolled if they have successfully completed the screening procedure outlined above. This study will be monitored by the DSMC specified above.

After being enrolled in the study, participant safety will be monitored regularly by the PI with reports being sent to the DSMC quarterly, in advance of the meetings.

As this is a minimal risk psychosocial activity intervention no AEs or SAEs are expected per NIH definitions, as it is unlikely that the risks of the study will affect medical outcomes or occurrences. However, if any AEs do occur, whether they appear study-related or not, they will be reported to the DSMC and the IRB within 48 hours of occurrence. Any deaths to study participants, from whatever cause, will be reported within 24 hours. The DSMC and IRB will then make the determination of whether they should be reported to the NIA.

If any AEs or SAEs occur, the PI will, with the assistance of the DSMC, determine if any modifications need to be made to the study protocol and procedures.

13.1 Specification of Safety Parameters

Safety parameters for the control condition will be assessed after each single session is completed, by clinical assessment. For experimental session (SHARE), safety parameters will be assessed after each session, also by clinical assessment. Criteria for concern includes adverse behavioral changes, significant change in diagnosis or prognosis, and suicidal ideation. If a participant reports changes at the start of a session, the SHARE Counselor will immediately notify the study team, and programming will either resume or stop, depending upon the nature of the report. If information is shared that falls within the identified criteria for concern at any point, the SHARE Counselor will be instructed to contact the study PI immediately for guidance. If this occurs at a clinical level that then results in an AE it will be reported to the DSMC and IRB.

13.2 Methods and Timing for Assessing, Recording, and Analyzing Safety Parameters

The risk profile for this study is low as it is a minimal risk, nonpharmacologic intervention. As such, assessing and recording of the parameters will be done by the PI with the end goal of informing the DSMC of any deviations. Since the PI and team of consultants will be intimately involved in all aspects of the trial, all subject data will be regularly reviewed by them and all staff will report to them on an ongoing basis, assuring that all issues are recorded on a timely basis and any AEs or SAEs are reported to the DSMC within 24-48 hours. The DSMC will be responsible for analyzing the associated data and determining if there are any study-related issues that need to be intervened upon.

Adverse Event (AE): Any untoward or unfavorable medical occurrence in a clinical research study participant, including any abnormal sign (e.g. abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participants' involvement in the research, whether or not considered related to participation in the research.

Serious Adverse Event (SAE): 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

Safety reports will be sent to the DSMC quarterly and will include a detailed analysis of study progress, AEs, and SAEs.

13.3 Reporting Procedures

AEs and SAEs will be reported to the DSMC and the IRB by the PI within 48 hours of occurrence. Any deaths to study participants, from whatever cause, will be reported within 24 hours. The DSMC and IRB will then make the determination of whether they should be reported to the NIA. The severity of AEs and SAEs will be determined by the PI and Experimental Team Leader in consultation with the DSMC. The events will be recorded on the "Adverse Events Reporting Form" which includes the instructions for both where the form should be submitted and filed, as well as the reporting timeline required.

How AEs will be classified:

13.4 Severity of Event

All AEs will be assessed by a qualified medical professional. Events will be graded using the criteria below. Since this is a non-medical study, no toxicity tables or like criteria can be utilized.

For adverse events (AEs) the following guidelines will be used to describe severity.

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."

13.5 Relationship To Study Intervention

All AEs will have their relationship to study participation assessed with a level of specificity appropriate to the non-pharmacological study design. This study will use a binary assessment (related/not related) for determining AEs. Evaluation of relatedness will consider etiologies such as natural history of the underlying disease, concurrent illness, concomitant therapy, study-related procedures, accidents, and other external factors.

All adverse events (AEs) must have their relationship to study intervention assessed by a qualified medical professional who examines and evaluates the participant based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below. In a clinical trial, the study product must always be suspect.

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 intervention administration and cannot be explained by concurrent disease or other drugs or chemicals. The response to withdrawal of the study intervention (rechallenge) should be clinically plausible. The event must be pharmacologically or phenomenologically definitive, with use of a satisfactory rechallenge procedure if necessary.

Not Related – The AE is completely independent of study intervention administration, and/or evidence exists that the event is definitely related to another etiology. There must be an alternative, definitive etiology documented by a qualified medical professional.]

13.6 Follow-up for Adverse Events

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during study visits and interviews of a study participant presenting for medical care, or upon review by a study monitor.

All AEs including local and systemic reactions not meeting the criteria for SAEs will be captured on the appropriate case report form (CRF). Information to be collected includes event description, time of onset, qualified medical professional's assessment of severity, relationship to study product (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 must be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

Any medical 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. AEs characterized as intermittent require documentation of onset and duration of each episode.

The PI will record all reportable 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.

13.7 Unanticipated Problems

Upon notification of an Unanticipated Problem, the Experimental Team Leader will notify all appropriate parties as described in the protocol:

The Experimental Team Leader will immediately notify the Principal Investigator.

The PI will send a notification email to the IRB.

The PI will advise the Study Team regarding screening, enrollment, and ongoing participation. Upon advisement by the IRB, the Principal Investigator will determine the study's status and notify the Study Team.

14.0 STUDY COMPLIANCE

The PI will maintain a Protocol Deviation / Violation Log, in which she will report of all protocol deviations/violations. All such deviations / violations will be reported to the Data and Safety Monitoring Committee (DSMC), including but not limited to the following:

- Enrollment of an ineligible participant
- Failure to obtain Informed Consent
- Visits or procedures conducted outside of the protocol specified window
- Failure to keep IRB approval up-to-date
- Wrong treatment administered to participant
- Follow-up visit at a time point different from that specified in the protocol

15.0 DATA COLLECTION AND STUDY FORMS

Below is a list of documents that will be used in the study:

Screening

- Dementia Rating Scale (DRS)
- Montreal Cognitive Assessment (MoCA)

DYAD

Baseline Assessments

- Service Availability Measure
- Care Values Scale (CVS)
- Preferences for Care Tasks Scale (PCTS)
- Dyadic Relationship Scale (DRS)
- Personal and Instrumental Activities of Daily Living (PADL & IADL)
- Emotional-Intimacy Disruptive Behavior Scale (EIDBS)
- Dementia Quality of Life +/- Affect
- Center for Epidemiological Studies Depression Scale (CES-D)
- Stress in Providing Care
- Leisure & Healthy Behaviors
- Quality of Life – AD (QoL-AD)

Follow Up Assessments

- Service Availability Measure
- Care Values Scale (CVS)
- Preferences for Care Tasks Scale (PCTS)

- Dyadic Relationship Scale (DRS)
- Personal and Instrumental Activities of Daily Living (PADL & IADL)
- Emotional-Intimacy Disruptive Behavior Scale (EIDBS)
- Dementia Quality of Life +/- Affect
- Center for Epidemiological Studies Depression Scale (CES-D)
- Stress in Providing Care
- Leisure & Healthy Behaviors
- Quality of Life – AD (QoL-AD)
- Satisfaction with SHARE/Control Sessions

Counselors

- Post Session Evaluations

15.1 Source Documentation

Source documents for this study include demographics forms, standardized test forms, satisfaction questionnaires, clinical notes, and post session evaluation etc. All source documents are electronic. This method reduces the likelihood of transcription errors. All data will be checked and cleaned during a QA process to ensure data integrity.

All essential study documents will be retained by the study team in an electronic Participant Folder and include:

- Source documents
- Signed informed consent forms
- Assignment sheets
- Electronic case files including clinical notes
- Data correction forms
- Applicable Notes to File

At conclusion of study, all source documents and other required documentation is kept with study records as required by protocol and IRB guidelines.

15.2 Forms Maintenance

All forms will be stored in electronic participant folders on the Benjamin Rose server. Forms which are collected digitally will automatically be saved to a secure, HIPAA-compliant database to the correct participant folder. Hard copy forms, if any, will be scanned and placed into the proper electronic folder, then shredded.

15.3 General Instructions for Completing Forms

For All forms:

- All data collection forms should be filled out electronically, with fillable pdfs or through REDCap, unless internet is unavailable.
- Other forms, such as assignment sheets, should be saved in the participant's digital binder (file folder with their ID number)

- Naming Convention should be as follows:
- ID# Name of File MM/DD/YYYY/
- All forms need to be reviewed by the PI before being exported or entered into SPSS.
- The PI will guide all updating of forms, as needed.
- The PI will review and approve all changes to forms.
- During the weekly meeting, issues with data collection, including possible problems with forms should be discussed by study team members.
- Be sure to completely fill out all forms.
- Participants must not be identified by name on any study document submitted with the forms. Replace the participant's name with the participant identification (ID) number.
- Time: Use a 24-hour clock (e.g., 14:00 to indicate 2:00 p.m.) unless otherwise specified.
- Dates: All dates must be verifiable by source documents. Historical dates are sometimes not known (e.g., date of first symptom); therefore, conventions for missing days and/or months should be described (e.g., UNK or 99).
- Abbreviations: Use of abbreviations not specifically noted in the instructions for completing the forms can be problematic and should be held to a minimum.
- Skipping items: Do not skip any items. Some items may carry "Unknown" or "Not Applicable" response choices which should be checked when necessary.
- Incomplete data: Data may not be available to complete the form for various reasons. Note the item for which data is not available in the Excel spreadsheet and indicate the reason near the appropriate field:
- If an evaluation was not done, note ND and provide a reason.
- If the information is not available, but the evaluation was done, note NAV.
- Only in rare circumstances, as in the case of lost documentation, should NAV be recorded on the spreadsheet. Every effort should be made to obtain the information requested.
- If an evaluation is not applicable, write NA.
- Incomplete or Illegible forms: Incomplete documentation that does not have adequate explanation (as described above) compromise the integrity of the entire study and will be immediately addressed by the PI.

15.4 Data Flow

Completed forms (whether electronic or hard copy) will be reviewed by the Experimental Team Leader to ensure completeness and accuracy. Any errors will be crossed out, corrected, and then initialed. Once the form has been reviewed and corrected (if needed), the form will be initialed on the bottom in the following way: form reviewed [and corrected] by DW on 7/30/21. This form is ready for data entry." If any accidental references to the person by name is included on the data form, such references will be redacted and initialed. Data from the form will then be entered into the study's master database by the research assistant.

15.5 Administrative Forms

The following administrative forms will be used: Screening and Enrollment Log and Staff Training Log.

15.6 Retention of Study Documentation

After the study ends, study staff shall maintain participant forms in a secure location for 3 years, as indicated by the protocol, federal regulations, and IRB guidance.

16.0 DATA MANAGEMENT

Data Tracking will be conducted in the following way:

- The Research Team will manage a data tracking spreadsheet. Each row will contain a participant ID and each column will contain a piece of data required for the study. This will support tracking data that have been completed and which data will need to be completed (and by when). Once data are collected, the Project Coordinator will note the person who collected the data and on what date (e.g., Collected by XX on x/xx/xx). It should be noted that separate data tracking worksheets will be maintained for each type of participant (PWD, CG, and Counselor).

Study Form Review will be conducted in the following way:

- Completed electronic forms will be reviewed by the Research Team to ensure completeness and accuracy. Any errors will be noted in the above Excel spreadsheet, corrected, and initialed. Once the form has been reviewed and corrected (if needed), the Excel doc will be noted in the following way: form reviewed [and corrected] by XX on x/xx/xx." If any accidental references to the person by name is included on the data form, such references will be redacted and initialed.

Data Collection will be conducted in the following way:

- Research Interviewers will conduct Baseline, Follow-Up, and Post-Session Evaluation data over the telephone with PWD and CG, separately. They will enter data directly into REDCap by clicking on the links delivered through their secure MyCap accounts. Once entered, the Project Coordinator will double-check the entered data to ensure accuracy. If any questions arise or data are missing, the Project Coordinator will contact the Research Interviewers to correct any errors. These corrections will be noted in the Excel document.

Data Analyses will be conducted in the following way:

- The PI, with the assistance of the Statistical Consultant (Dr. Talea Cornelious) will conduct data analyses utilizing SAS, R, and SPSS.

16.1 Quality Control Procedures

All study staff responsible for data collection and management have received human subjects and good clinical practice training/certification. In terms of training for collection of other measures and adherence to other study protocols, all staff will be trained via standard, in-person or remote training protocols on all measures.

16.2 Data and Form Checks

Before data are exported, the Research Team will check the REDCap forms for the following possible issues:

- Missing data (e.g., skipped items or sections)

- Out-of-range or erroneous data
- Inconsistent and illogical session dates over time
- Data inconsistency across forms and visits
- Not completing all fields of a "completed form" or no reason for missing data is provided

16.3 Site Monitoring

This is a single-site clinical trial, since there is one study site (Benjamin Rose) conducting and coordinating the study protocol. As such, the PI will be jointly responsible for the following monitoring activities:

- Ensuring the rights and safety of participants
- Confirming that the study is conducted in accordance with GCP guidelines
- Ensuring maintenance of required documents
- Verifying adherence to the protocol
- Monitoring the quality of data collected
- Ensuring accurate reporting and documentation of all AEs and unanticipated problems

The study team will meet weekly about the project and each of the above items will be part of the meeting agenda each week. Researchers will voice any concerns or issues related to the above areas during the meeting.

17.0 DATA AND SAFETY MONITORING

There is a data and safety monitoring committee that will meet quarterly for discussion. This team will consist of the following individuals:…

The roles and responsibilities of the entities monitoring participant safety and study quality are described in this section. All clinical trials supported by NIA must have a data and safety monitoring plan. The type of safety monitoring is determined by the size and/or nature of the study and is specified in the Notice of Grant Award. Small, single-site studies usually have a Safety Officer. This study has been assigned an SO by NIA.

17.1 Reports

The following reports will be produced for this study:

Enrollment Reports

- Presented to PI weekly beginning 7 days after 1st enrollment and then every seven days until Enrollment is completed
- Screening and enrollment data are entered by Research Assistant and report is produced by Project Coordinator

Data Tracking Reports

- Delivered to PI once per week once data collection begins
- Produced by Project Coordinator

Safety Reports

- Delivered to the DSMC quarterly and will include a detailed analysis of study progress, AEs, and SAEs.
- Produced by the PI

Final Report

- Delivered to NIH and the SO no more than 120 days after the completion of the project.
- Produced by the PI and Statistical Consultant with assistance from the Project Coordinator and Research Assistant

17.2 Study Completion and Close-Out Procedures

The following study completion and close-out procedures will be used:

- The PI and/or Experimental Team Leader will verify that study procedures have been completed, data have been collected, and study intervention(s) and supplies are returned to the responsible party or prepared for destruction.
- The PI will ensure that all data queries have been completed.
- The PI will ensure that correspondence and study files are accessible for external audits.
- The PI will ensure that the study records are maintained and any relevant study information reported to the NIA.
- The PI will notify the IRB of the study's completion and store a copy of the notification.
- The PI will prepare a report summarizing the study's conduct.
- The PI will notify participants of the study completion.

17.3 Participant Notification

A close out letter will be sent to participants, with a summary of key results. The letter will also thank them for participating in the study. The PI will have lead responsibility for creating the letter and making sure it is sent to all participants.

17.4 Confidentiality Procedures

The following confidentiality safeguards will be used:

- Electronic files – Data identifying participants that are stored electronically will be maintained in a separate file that is saved on a secure, HIPAA-compliant server.
- Forms – Forms or pages containing personal identifying information will be separated from other pages of the data forms and be retained in a secure location.
- Data listings – Participant name, ID, name code, record number, and other unique identifiers will not be included in any published data listing.
- Data distribution – Data listings that contain participant name, name code, or other identifiers easily associated with a specific participant will not be distributed.
- Data disposal – Computer listings that contain participant-identifying information will be disposed of in an appropriate manner.
- Access – Participant records will not be accessible to persons outside the site without the express written consent of the participant.
- Storage – Study forms and related documents will be retained both during and after study completion and will be stored in a secure location
- Passwords – Passwords will be used to provide limitations on general access to computer systems and to

the functions that individuals can use. Passwords will be changed on a regular basis.

- User Training – Study staff with access to computer systems will be trained in their use and in related security measures. Training will include explanations of how to access the system and a discussion of the need for, and importance of, system security.
- System Testing – Prior to the use of a new computer system, and after any modifications, the system will be tested to verify that it performs as expected. Testing will verify that the password-activated access system performs as intended.
- System Backups – Backup copies of electronic data will be made on a regular basis.

17.5 Publications

Study results will be made available to the public as soon as possible. Publication of the results of this trial will be governed by the policies and procedures of Benjamin Rose, NIH guidelines, and standard industry practice. Any presentation, abstract, or manuscript will be made available for review by the sponsor and the NIA prior to submission.

18.0 MOP MAINTENANCE

The MOP will be updated on an as needed basis. When a new revision is made, the following procedure will be followed:

- The version date on the cover page and footer will be updated with the latest date.
- The new version date will be added to the Versions Page, along with the name of the person who made the changes (usually the PI), and a list of the key changes / additions that were made to the MOP.
- Previous versions of the MOP will be maintained and saved in a folder on the Benjamin Rose server.