The Alzheimer's Companion Engagement (ACE) Project Study Protocol
02/19/2025

Study Title	The Alzheimer's Companion Engagement (ACE) Project. Also known as The ACE Project.
Principal Investigator	Sheria Robinson-Lane, PhD, RN
Study Design	A cross-sectional intervention pilot study with a sample size of 36 is proposed. Participants will be assembled into small groups of 2 - 5 to complete an 8-week, video conferencing-based support program that has been developed intentionally to meet the multi-dimensional needs of Black ADRD family caregivers.
Study Sponsor	The National Institute on Aging of the National Institutes of Health (NIH)
Objectives/Aims	The overall objective of the proposed research is to test the feasibility of a culturally responsive approach to caregiver support that aims to promote adaptive coping and optimize health for Black ADRD family caregivers. Our Aims are as follows: **Aim 1:** To develop and pilot test a virtual intervention for Black family caregivers of persons with ADRD. We hypothesize that this study is feasible with identified clinical benefits (improved self-perceived physical health, reduced or maintained blood pressure, reduced pain intensity, improved self-perceived mental health, reduced depressive symptoms, and stress) that support further testing within a larger clinical trial. In addition, we hypothesize that the caregivers will demonstrate an increased ability to provide care for a person with ADRD (self-efficacy). **Aim 2:** To determine the estimated intervention effect size and evaluate study process outcomes. In addition to power analysis, the investigation will include a review of descriptive statistics and capturing of field notes to evaluate process outcomes including recruitment and protocol execution.
Rationale/ Significance	Alzheimer's disease is a leading cause of death in the United States and is a key contributor to cognitive and functional disability among older adults. In recent years, Alzheimer's disease-related mortality rates have significantly increased among Black Americans despite overall population declines in prevalence. Family caregivers of Black older adults with Alzheimer's disease and/or related dementias (ADRD) are most at risk for a new ADRD diagnosis. Although evidence has demonstrated that culture plays an important role in caregiver outcomes, few interventions have been designed to meet the needs of underserved ethnoracial minority populations. While some programs have included significant numbers of Black caregivers in their sample, they have not demonstrated significant improvements in chronic health outcomes, or have focused exclusively on the use of cognitive behavioral therapy (CBT) to improve psychosocial outcomes. Additionally, these programs have not adequately addressed other domains of care such as spirituality and caregiver physical health. This is particularly important in addressing ADRD-related health disparities between Black and White caregivers. There is a critical need for caregiver-informed health interventions that foster effective self-management of chronic disease and the use of personally-relevant

	ways of coping to manage stress. In addition to reducing risk of ADRD-related disability, culturally rooted and strength-based interventions can improve caregiver health, the perceived ability to provide care for a person with ADRD (self-efficacy), and increases the likelihood that caregivers will experience benefits from caregiving. In short, an effective intervention can improve the quality of life for caregivers, particularly older adult caregivers, and care recipients. Supporting caregiver health also facilitates aging in place for disabled older adults. Finally, the proposed work is significant as it will improve scientific knowledge of the effects of coping on family caregiver health, self-efficacy in caregiving, and the perceived rewards of caregiving.
Population	Black family caregivers of persons with ADRD thoroughly
Study Participation Duration	8 weeks
Phase	Behavioral Clinical Trial
Description of Intervention	The proposed intervention is a peer-supportive and facilitator-led video teleconference program that will engage small groups of caregivers weekly over 6 weeks (the first and last weeks are for survey completion and program evaluation). Each week participants (n = 36, 2-5/group) will receive a different culturally relevant caregiving or personal health strategy to practice. During the support calls, a facilitator will provide an overview of the content covered and each participant will have the opportunity to discuss their past week and how they engaged the weekly strategy, or challenges that came up for them during the week. The format will be structured to ensure that core content is reviewed, and everyone can be equally engaged while flexible enough that caregivers can receive support in the areas they need. A battery of assessment measures will be taken at weeks 1 and 8.
Estimated Time to Complete Enrollment	2 months
Key Eligibility Criteria	Inclusion criteria for participation are as follows: 1. Self-identified as Black/ African American 2. At least 18 years old 3. Able to speak, understand, and hear spoken English 4. Related to, or has a close personal relationship to a person over the age of 55 that has an ADRD diagnosis or evidence of cognitive impairment 5. Regular access to a smartphone, tablet or computer with internet access that will allow video conferencing engagement. 6. Provides monitoring, and assistance in activities of daily living and or other care tasks for the care recipient.
Primary Outcome Measure	Caregiver self-efficacy will be measured by the Revised Scale for Caregiving Self-Efficacy, which evaluates the caregivers' ability to obtain respite care, respond to disruptive behaviors, and control one's own upsetting thoughts about caregiving.
Secondary Outcome	Positive Aspects of Caregiving will be an additional outcome measure. The Positive Aspects of Caregiving tool is a brief tool that asks questions

Measures	about caregiving experiences that made the caregiver feel good about providing care.
Additional Assessment Measures	**Caregiver** Demographics – Demographic questionnaire Care Task List Caregiver Community Survey 4 Self-Perceived Physical Health - PROMIS Global Health Scale (V1.2) Self-Perceived Mental Health – PROMIS Global Health Scale (V1.2) Blood Pressure – Electronic blood pressure cuff reading (participant reported) Anxiety – PROMIS Emotional Distress Anxiety 4Aa Depression – PROMIS Emotional Distress Depression 4a Stress – Psychological Stress Measure-9 Adaptive Coping – Coping and Adaptation Processing Scale Personal Resources – Personal Resource Questionnaire (PRQ2000) Religious involvement – Duke University Religion Index Cultural Socialization to Display Strength – Superwoman Schema Scale **Relative (answered by caregiver)** Physical support needs (ADLS)– Barthel Index of Daily Living Instrumental support needs (IADLS) – Instrumental Activities of Daily Living Scale Reporting of Neuropsychiatric Symptoms – Neuropsychiatric Inventory Questionnaire (NPI-Q)
Protocol	1. Participants will be recruited through study flyers distributed in the metro-Detroit area, FaceBook campaigns, and service organizations that support persons with dementia and their caregivers. Flyers will contain a QR code and link that takes participants directly to a Qualtrics screening survey where they may enter their contact information. Flyers also contain a study email address through which they may contact the research team (umsn-caregiverstudies@med.umich.edu) or the study PI (grices@umich.edu) for more information. 2. Data from all individuals completing the screening form will be entered into an identifiable tracking form that includes data on study eligibility and participant contact information (e.g., name, email address, street address). Study ID numbers will be pre-assigned to all individuals using block randomization. NIA requires data collection on all screened individuals. The Tracking Form will serve as the study crosswalk to link participants to study IDs and reduce fraudulent study enrollment or duplicate enrollments. The identifiable tracking form will be stored within a HIPPA-compliant password-protected cloud file (DropBox). 3. A study team member will contact eligible participants and set up an appointment to verify identification via zoom and answer any

additional study-related questions participants may have. Zoom links for the verification visit will be emailed or sent via text depending on participant preference. A reminder email/ text message will go out the day prior to visit.

4. At the time of zoom verification meeting, the participant will hold their ID to the camera to verify identity and US address. Study team member will confirm the participant's address for remuneration, confirm the preferred method of receiving survey links, preferred methods of payment (gift card or check), and availability for participation in support group meetings. Study team member will update the participant enrollment tracking spreadsheet with payment and contact preferences.
5. Any participant not able to be verified will not proceed with the study. The eligible participant tracking form will note the reason for removal.
6. Study team member will email or text 1st survey link (depending upon participant preference) which contains the consent to participate at the start of the survey. Participants will have the option to print the electronic consent form from the device they are using to take the survey. A copy of the consent form will also be mailed along with other study materials (electronic blood pressure cuff and instructions).
7. Participants completing electronic consent will be added by ID number to the enrollment progression form which contains all data elements required elements by NIA for monthly enrollment reporting and information on study progression.
8. Study staff will schedule the initial incentive payment ($50), and mail the blood pressure cuff, instructions, copies of weekly educational materials, and copies of the consent form following completion of the 1st survey. (Participants may keep the blood pressure cuff at the conclusion of the study.)
9. Individuals will be removed from study if they do not complete the 1st survey after 4 weeks (or by the start of the last scheduled group meeting).
10. Once we have up to 5 participants with similar availability, we will initiate a group and provide participants with a schedule of assigned meeting dates/ times which will be sent out electronically by email or text message depending on their preference. Participants provide their general availability within the initial screening questionnaire. Availability is confirmed during the video verification visit.
11. Groups will meet every week via zoom and cover the following topics:
    a. Week 1 Overview of Dementia and Disease Progression
    b. Week 2 Self Care & Accessing Support
    c. Week 3 Managing Challenging Behaviors ($50 gift cards/checks sent following this meeting)
    d. Week 4 Pain Management
    e. Week 5 Accessing Support
    f. Week 6 Advanced Directives and End-of-Life Planning ($50

gift cards/checks sent following this meeting)

12. Weekly meetings will be scheduled for 1 hour and have time allocated as follows:
    a. 1st 5 minutes welcome. (Week 1 At the start of the meeting participants will also be reminded to maintain group confidentiality, be thought about what they choose to share, and will be offered the option use an alias in Zoom if they choose. Additional time should be allocated to allow for introductions of each participant noting their relationship to care recipient and how long they have been providing care. Limit to introductions to 1-2 minutes per person).
    b. 5-10 minute review of educational topic for the week
    c. 30-40 minutes sharing (time equally divided amongst participants to check-in regarding challenges or questions around the topic area. Time for each participant should include feedback time for the group to respond with requested support).
    d. 5-10 minutes closing to preview next topic, remind to submit blood pressure readings and review next expected steps of study. Closing should include time for brief participant reflection to note what they are thankful for that week or a joy they have experienced.
13. Each week a participants will receive a PDF copy (or picture image if receiving text messages) of the educational handout for the week. We will also send a Qualtrics survey link out to participants to provide their blood pressure reading for that week.
14. Blood pressure data will updated on blood pressure tracking sheet.
15. Any participants with a significantly abnormal blood pressure reading (systolic over 180 or less than 90; diastolic greater than 120 or less than 60) will be contacted by the study PI to encourage an additional reading to verify. Recommendations will be made as appropriate for follow-up with the participant's primary care physician, urgent care clinic, or hospital emergency department as appropriate.
16. After week 3 mid study remuneration will be sent out ($50)
17. After the final group meeting and addition payment will be sent out ($50) and the last electronic survey will be sent for completion.
18. A final gift card $50 will be mailed after receipt of last survey
19. All survey data from Qualtrics will be downloaded into Excel datasheets and matched by participant id number for analysis
20. Blood pressure data for participants will be added to the master data sheet from the Blood pressure tracking sheet.
21. Cleaned data will be uploaded to Stata (or other statistical analysis program).
22. The identifiable data tracking form will be deleted after the conclusion of the study following data analysis.
23. All data files will be maintained electronically in a HIPAA-compliant pass-word-protected cloud storage (e.g. DropBox). Deidentified datasets will stored on Deepblue at the conclusion of the study.

Analysis Plan	Descriptive statistics (frequency tables, means/ modes) and field notes will be used to evaluate process outcomes (recruitment feasibility, retention, protocol execution). While correlation analysis and basic linear modeling will be used to predict effect sizes for future study.

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