Easing the Burden of Dementia Caregiving: A Telephone-delivered Mindfulness Intervention for Rural, African American Families

NCT number:

NCT04058886

Version:

April 12, 2023

Study Chairman or Principal Investigator:

Susan A. Gaylord, PhD

Sharon W. Williams, PhD

Supported by:

The National Institute on Aging

1R21 AG061728-0

Study Intervention Provided by:

Not applicable

Sponsor of IND (IDE):

Not applicable

TABLE OF CONTENTS

PRÉCIS ..... **viii**

Study Title viii

Objectives viii

Design and Outcomes viii

Interventions and Duration ix

Sample Size and Population ix

STUDY TEAM ROSTER **10**

Principal Investigator: Name 10

Co-Investigators: Name 10

PARTICIPATING STUDY SITES **12**

1 Study objectives **12**

1.1 Primary Objective 12

1.2 Secondary Objectives 12

2 BACKGROUND AND RATIONALE **13**

2.1 Background on Condition, Disease, or Other Primary Study Focus 13

2.2 Study Rationale 14

3 STUDY DESIGN **16**

4 SELECTION AND ENROLLMENT OF PARTICIPANTS **19**

4.1 Inclusion and Exclusion Criteria 19

4.2 Study Enrollment Procedures 20

5 STUDY INTERVENTIONS **21**

5.1 Interventions, Administration, and Duration 21

5.2 Handling of Study Interventions 21
5.3 Concomitant Interventions 23
5.3.1 Allowed Interventions 22
5.3.2 Required Interventions 22
5.3.3 Prohibited Interventions 22
5.4 Adherence Assessment 22
6 STUDY PROCEDURES 23
6.1 Schedule of Evaluations 23
6.2 Description of Evaluations 24
6.2.1 Screening Evaluation 24
6.2.2 Enrollment, Baseline, and/or Randomization 25
6.2.3 Follow-up Visits 27
6.2.4 Completion/Final Evaluation 27
***7* SAFETY ASSESSMENTS 28**
7.1 Specification of Safety Parameters 29
7.2 Methods and Timing for Assessing, Recording, and Analyzing Safety Parameters 30
7.3 Adverse Events and Serious Adverse Events 29
7.4 Reporting Procedures 31
7.5 Follow-up for Adverse Events 31
7.6 Safety Monitoring 31
8 INTERVENTION DISCONTINUATION 33
9 STATISTICAL CONSIDERATIONS 33
9.1 General Design Issues 33
9.2 Sample Size and Randomization 35
9.2.1 Treatment Assignment Procedures 35
9.3 Interim analyses and Stopping Rules 35
9.4 Outcomes 36
9.4.1 Primary outcome 36
9.4.2 Secondary outcomes 36
9.5 Data Analyses 36

10 DATA COLLECTION AND QUALITY ASSURANCE 38

10.1 Data Collection Forms 38

10.2 Data Management 38

10.3 Quality Assurance 38
10.3.1 Training 38
10.3.2 Quality Control Committee 39
10.3.3 Metrics 39
10.3.4 Protocol Deviations 41
10.3.5 Monitoring 41

11 PARTICIPANT RIGHTS AND CONFIDENTIALITY 40

11.1 Institutional Review Board (IRB) Review 40

11.2 Informed Consent Forms 41

11.3 Participant Confidentiality 40

11.4 Study Discontinuation 40

12 ETHICAL CONSIDERATIONS 41

13 COMMITTEES 41

14 PUBLICATION OF RESEARCH FINDINGS 42

15 REFERENCES 42

16 SUPPLEMENTS/APPENDICES 48

16.1 ..... Appendix A: Adverse Event Monitoring Form……..48

16.2 Appendix B: Adverse Event Reporting Form……49
16.2 Appendix C: Consent Forms……51

TABLE OF FIGURES

Figure 1: Stress process and uncertainty theories informing caregiver mindfulness training 14

Figure 2: Intervention design

Protocol/IRB Change Log* (not all IRB changes necessitated protocol changes):

2/2019

1. Modified consent form to include Certificate of Confidentiality language

9/2019

1. Added new personnel (Elondra Harr, research assistant)
2. Updated flyer and consent forms to include more details, including increasing reimbursement offered (increased total reimbursement from $50 to $100)

12/2019

- Updated screening script to match consent form and flyer language
- We inserted the short form, used in place of the long form (where appropriate), for quantitative measures to decrease participant burden. Measures that will use the short form include:
    - Zarit Burden Interview-SF 12 (ZBI-12)
    - Intolerance of Uncertainty (IUS-12)
    - Cognitive Emotion Regulation-Short Form (CERQ-18)
    - PROMIS General Self-efficacy-Short Form 4a
    - PROMIS Self-efficacy Manage Emotions-Short Form 4a
    - PROMIS Anxiety-Short Form 4a
    - PROMIS Anger-Short Form 5a
    - PROMIS Emotional Support-Short Form 4a
    - PROMIS Instrumental Support-Short Form 4a
    - PROMIS Informational Support-Short Form 4a
- Pre-participation Interview: guided questions added for participants to share their thoughts about mindfulness, telephone sessions, and comfortability with technology
- Mindfulness scale: substituted Cognitive and Affective Mindfulness Scale-Revised (CAMS-R) for Self-Compassion Scale (SCS). Questions for CAMS-R are shorter. The research team thought this would decrease the questionnaire burden for participants.
- Added new personnel (Karen, Sheffield-Abdullah, co-investigator)

3/2020:

1. In response to COVID, we changed the protocol as follows:
    a. All assessments and consent processes could be completed over the telephone (in home left as an option)

b. The 3.5 hour in-person retreat was changed to a 1.5 hour video-conference retreat

4/2020:

1. Added new recruitment methods in response to COVID, including email announcements, radio/newspaper ads, and Facebook ads
2. Added new personnel (Nandie Elhadidy, Rachel Mason, research assistants)
3. Modified eligibility criteria for care recipients. Recipients would be considered eligible if care recipient has received a diagnosis of dementia, OR receives a score of 2 or higher rating by the primary caregiver on the AD-8 scale OR at least an 8 on the FAST scale.

6/2020:

1. Minor flyer update to emphasize over the phone options
2. Expanded geographic eligibility area to include all of rural Eastern NC (and defined these)
3. Received IRB approval to allow community partners to share potential subjects contact information with the team, if permission by the potential subject is given

7/2020:

1. Added website site (Study Pages) and NC registry for Brain Health/Duke Family Caregiver e-news as recruitment sources

8/2020:

1. Updated study personnel, added Dr. Jessica Barnhill as study physician

9/2020:

1. Consent modified to state online retreat length could vary (up to 4 hours)

10/2020:

1.Added questions to enrollment process to assess home internet status, for purposes of distribution of tablets

12/2020

1. Added emergency contact information and a UNC consent addendum to allow unencrypted texting/emailing for primarily to allow scheduling and reminders of study-related activities
2. Added protocol for emergency situations over the phone

7/2021

1. Added Jenni Shafer to the research team

10/2021

1. Added script/instructions to assessments to emphasize voluntary nature/ability to skip questions

PRÉCIS

Study Title: Easing the Burden of Dementia Caregiving: A Telephone-delivered Mindfulness Intervention for Rural, African American Families

Objectives

SPECIFIC AIM 1: To determine the feasibility and acceptability of a telephone-delivered mindfulness training intervention (TMT) in decreasing caregiver burden among rural, African American, informal caregiving teams of people with dementia.

SPECIFIC AIM 2: To explore, on a preliminary basis, the effects of the training on caregiver burden and relevant secondary outcomes for both caregiving team members, including (1) emotion regulation; (2) tolerance of uncertainty; (3) emotional and physical health; (4) family conflict within the informal caregiving team; and (5) self-efficacy.

SPECIFIC AIM 3: To explore comfort with and willingness to adopt technologies (e.g. telephone-based, web-based) to access mindfulness practices and existing caregiving educational resources.

Design and Outcomes

The proposed study utilizes a single-group, uncontrolled design to assess the feasibility and acceptability of telephone-delivered mindfulness training designed to alleviate caregiver burden for rural caregivers of African American individuals with moderate to severe dementia, A care partner—the person who provides the most support in addition to the primary caregiver—is included in the intervention. The primary outcome is feasibility as assessed by an 85% retention rate with completion of at least 6 of the intervention sessions. Pre- and post-participation interviews will assess acceptability.

At baseline, after obtaining informed consent, study staff will interview primary caregivers in their homes (or via a phone call post-COVID) and will administer a set of questionnaires, including the 12-item Zarit Burden Interview as well as measures of:

1) family satisfaction;
2) tolerance of uncertainty;
3) cognitive emotion regulation;
4) general self-efficacy;
5) anxiety and anger;
6) self-efficacy in managing emotions;
7) global physical health;
8) family conflict;
9) social support (emotional, instrumental, informational);

10) meaning and purpose;
11) cognitive and affective mindfulness

Study staff will interview the care partner in person or over the telephone. After the 8-week intervention, study staff will interview the caregiver (in the home, or via telephone), care partners (on the telephone) once more, and administer the questionnaires.

Interventions and Duration

The intervention consists of mindfulness training delivered by telephone once weekly for 8 weeks. The intervention also includes one weekend part-day retreat.. The intervention, based on Kabat-Zinn's mindfulness-based stress reduction (MBSR) and adapted for this study population, emphasizes the following: 1) mindful experiencing, including mindfulness of body sensations, feelings, thoughts and emotions ; 2) mindful communication, including non-verbal mindfulness, mindful listening, and mindful speaking; and 3) mindful compassion for self and others.

Sample Size and Population

Planned study participants include 32 adult caregivers, aged 18 and older, who live with or near an African American dementia care recipient and provide at least four hours of care per day. Additional participants include an additional adult, the care partner, who the caregiver identifies as another person who helps with the care. This person may be a blood relative or a non-blood relative. Hence, 32 caregiver-care partner dyads comprise the study population.

STUDY TEAM ROSTER

Principal Investigators:

Susan A. Gaylord, PhD **Director, Program on Integrative Medicine**
Associate Professor, Dept. of Physical Medicine & Rehabilitation

184 Medical School Wing D, CB#7200
University of North Carolina at Chapel Hill
Chapel Hill, NC 27599-720
Tel: 919-966-8586\Fax: 919-843-5452
gaylords@med.unc.edu

Main responsibilities/Key roles: Fiscal and administrative management, intervention refinement, regulatory communication, qualitative analysis, and data interpretation.

Sharon W. Williams, PhD, Director, Division of Speech and Hearing Sciences
Associate Professor, Department of Allied Health
3130 Bondurant Hall, CB#7190
University of North Carolina at Chapel Hill
Chapel Hill NC 27599-7190
Telephone: (919) 966-9462; Fax: (919) 966-0100
sharon_w_williams@med.unc.edu

Main responsibilities/Key roles: Project implementation, analysis and implementation of recommendations from key informants and advisory council members as well as intervention participants, development of caregiver resources, data analysis and interpretation.

Co-Investigators:

Keturah Faurot, PhD, PA, Assistant Director, Program on Integrative Medicine
Asst. Professor, Dept. of Physical Medicine & Rehabilitation
171 Medical School Wing D, CB#7200
University of North Carolina at Chapel Hill
Chapel Hill, NC 27599-720
Tel: 919-966-3578\Fax: 919-843-5452
faurot@med.unc.edu

Main responsibilities/Key roles: Protocol development, data management, and data analyses.

Christine Lathren, MD, MPH; Faculty Affiliate, Program on Integrative Medicine
Asst. Professor, Dept. of Physical Medicine & Rehabilitation
186 Medical School Wing D, CB#7200
University of North Carolina at Chapel Hill
Chapel Hill, NC 27599-720
Tel: 919-966-9656\Fax: 919-843-5452
lathren@email.unc.edu

Main responsibilities/Key roles: Caregiver handbook development (caregiver education and mindfulness training) development, qualitative data analyses.

Isabel Roth, DrPH; Faculty Affiliate, Program on Integrative Medicine
Asst. Professor, Dept. of Physical Medicine & Rehabilitation
186 Medical School Wing D, CB#7200
University of North Carolina at Chapel Hill

Chapel Hill, NC 27599-720
Tel: 919-966-9656\Fax: 919-843-5452
iroth@email.unc.edu

Main responsibilities/Key roles: Assist with recruitment, community engagement, including key informant interviews.

Jessica Barnhill, MD; Study Physician, Program on Integrative Medicine;
Faculty Affiliate, Program on Integrative Medicine
Asst. Professor, Dept. of Physical Medicine & Rehabilitation
186 Medical School Wing D, CB#7200
University of North Carolina at Chapel Hill
Chapel Hill, NC 27599-720
Tel: 919-966-9656\Fax: 919-843-5452
jbarnhill@med.unc.edu

Main responsibilities: Safety protocols, adverse events consultations

Karen Sheffield-Abdullah, Asst. Professor, School of Nursing
University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Main responsibilities: Safety protocols, adverse events consultations

Main responsibilities: Qualitative data analysis, mindfulness instructor

OTHER STUDY TEAM MEMBERS:

Jenni Shafer, PhD; T32 Post-doctoral Fellow, Program on Integrative Medicine
187 Medical School Wing D, #7200
University of North Carolina at Chapel Hill
Chapel Hill, NC 27599-720
Tel: 919-966-8586
Jenni_Shafer@med.unc.edu

Main responsibilities/Key roles: qualitative data analyses

Kelly Eason, BA; Coordinator, Program on Integrative Medicine; Research Assistant;
185 Medical School Wing D, #7200
University of North Carolina at Chapel Hill
Chapel Hill, NC 27599-7200
Tel: 919-966-8586
Kelly_Eason@med.unc.edu

Main responsibilities/Key roles: intervention assistant

Elondra Harr; Research Assistant;
185 Medical School Wing D, #7200
University of North Carolina at Chapel Hill
Chapel Hill, NC 27599-7200
Tel: 919-966-8586
Kelly_Eason@med.unc.edu

Main responsibilities/Key roles: intervention assistant

PARTICIPATING STUDY SITES

Not applicable.

1 STUDY OBJECTIVES

1.1 Primary Objective

SPECIFIC AIM 1: To determine the feasibility and acceptability of a telephone-delivered mindfulness training intervention (TMT) in decreasing caregiver burden among rural, informal caregiving teams caring for African Americans with dementia.

Hypothesis 1: TMT will be feasible within the informal caregiving teams. Feasibility is established when 85% (95% CI: 72.5, 97.5) of participants in the telephone-delivered mindfulness training intervention complete at least six sessions of the intervention.

Hypothesis 2: The adapted TMT will be acceptable to informal caregiving teams as evidenced by an 85% (95% CI: 72.5, 97.5) endorsement of the program in post-participation interviews.

1.2 Secondary Objectives

SPECIFIC AIM 2: To explore, on a preliminary basis, the effects of the training on caregiver burden and relevant secondary outcomes for both caregiving team members, including:

Hypothesis 1: Compared with baseline levels, we hypothesize that mindfulness training will reduce caregiver burden (Zarit Burden Interview).

Hypothesis 2: Compared with baseline levels, we hypothesize that mindfulness training will improve emotion regulation by increasing positive coping styles (acceptance, positive refocusing, positive reappraisal) and decreasing negative coping styles (rumination, catastrophizing, self-blame) as measured by the Cognitive Emotion Regulation Questionnaire.

Hypothesis 3: Compared with baseline levels, we hypothesize that mindfulness training will increase tolerance of uncertainty as measured by (an adapted form of) the Intolerance of Uncertainty Scale.

Hypothesis 4: Compared with baseline levels, we hypothesize that training in mindful communication will increase perceived social support among the caregivers (PROMIS Social Support short forms).

Hypothesis 5: Compared with baseline levels, we hypothesize that training in mindful communication reduce family conflict around caregiving (Family Conflict Scale).

Hypothesis 6: Compared with baseline levels, we hypothesize that mindfulness training will reduce anger and anxiety (PROMIS scales).

Hypothesis 7: Compared with baseline levels, we hypothesize that mindfulness training increase global self-perceived physical health (PROMIS short forms).

Hypothesis 8: Compared with baseline levels, we hypothesize that mindfulness training increase meaning and purpose (PROMIS short form).

Hypothesis 9: Compared with baseline levels, we hypothesize that mindfulness training along with a caregiver resources handbook will increase caregiver general and emotional self-efficacy (PROMIS scales).

Hypothesis 10: Compared with baseline levels, we hypothesize that mindfulness training will increase family satisfaction (Family Satisfaction Scale).

Hypothesis 11: Compared with baseline levels, we hypothesize that mindfulness training will increase mindfulness (Cognitive and Affective Mindfulness Scale).

SPECIFIC AIM 3: To explore comfort with and willingness to adopt technologies (e.g. telephone-based, web-based) to access mindfulness practices and existing caregiving educational resources.

As part of intervention planning, using interviews, we will investigate comfort with a smartphone/tablet. We will implement the tablets among half of the intervention groups so that we can compare acceptance between groups with and without the technology.

2 BACKGROUND AND RATIONALE

2.1 Background on Condition, Disease, or Other Primary Study Focus

The number of individuals and families impacted by Alzheimer's disease and related dementia (ADRD) is projected to triple by 2050 and many of those impacted will be African Americans (AAs).[1] Further, many older AAs live in rural areas and experience disadvantages by living in areas with fewer resources and poorer infrastructure.[2] Given that AAs and rural older adults are often disproportionately affected by ADRD, this research seeks to meet the need for culturally and geographically tailored research for rural AA caregivers of older adults with ADRD.[1,3–6] Most families, including AA families, provide dementia care in the home and when compared with other caregivers (CGs), dementia CGs experience higher levels of physical, financial, and emotional burden, including anxiety and stress as well as higher rates of family discord.[16–19,9] One study reported over 50% of spousal CGs and over 80% of adult children CGs endorsed some level of family conflict.[10] Some researchers have called dementia 'the great divider', as caregiving stress tends to accentuate long-standing interpersonal issues between family members.[11] Aspects of family functioning most strongly associated with caregiving burden include ineffective communication and difficulties around roles (i.e. distribution of caregiving tasks).[12] In AA families, often a cultural expectation of high family involvement exists,[13] so family conflict around roles and provision of social support may be particularly distressing.[14] Despite these findings, few CG interventions address family relationship difficulties.

We know that race and cultural experiences, ways of coping, and ways of seeking help often differ for AA compare with caregivers of other ethnicities.[15–18] Evidence also suggests that, contrary to previous findings, AA caregivers, who are likely to be adult children, also experience high levels of anxiety and distress.[19,20] Therefore, within-group studies of African Americans, and other racial minorities, are needed to provide characteristics and processes critical for tailored interventions.[21] Hence, **innovative theory-based programs**, culturally and geographically tailored to rural AA populations, are needed to ease the burden of dementia-related caregiving in rural AA populations.

2.2 Study Rationale

Pearlin et al.'s Stress Process Model posits complex relationships between background characteristics (demographics), primary stressors (care recipient neuropsychiatric symptoms and level of functional and cognitive impairment), secondary stressors/outcomes (interpersonal and intrapersonal strain) and caregiver health outcomes (physical and mental health) all mediated by coping and social support.[22] The theory conceptualizes family conflict as a secondary, but potent source of stress outside of the caregiving situation, with both direct and indirect effects on negative caregiver (CG) outcomes.[22] Family conflict is associated with high CG burden and negative CG mental and physical health outcomes,[10,23–25] even after controlling for CG and care recipient characteristics typically associated with stress outcomes. Moreover, there is evidence that the structured, often repetitious ways that family members interact with one another, can either promote positive CG outcomes or contribute to CG distress in families caring for someone with dementia.[26] In addition to these interpersonal strains, intrapersonal stressors such as role captivity and poor self-efficacy both result from and contribute to negative health outcomes.[22]

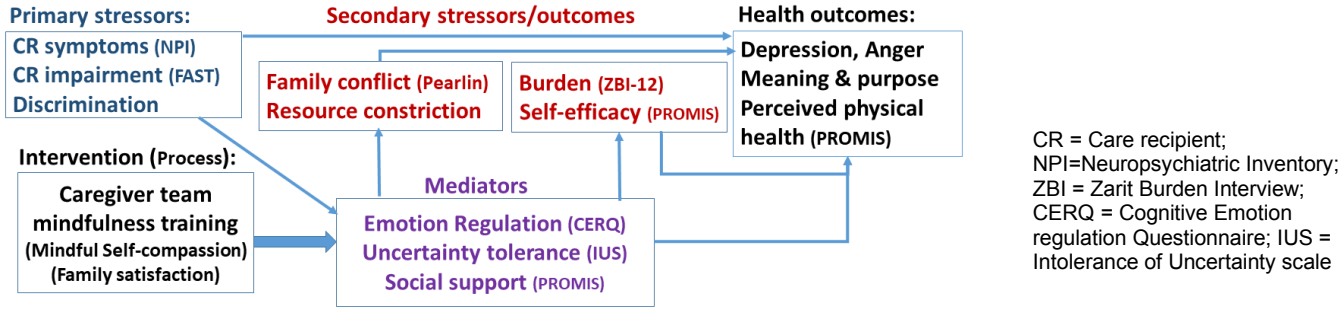

Figure 1: Stress process and uncertainty theories informing caregiver mindfulness training

Mishel's Reconceptualized Uncertainty in Illness Theory (RUIT),[27,28] like her original theory**,** conceptualizes uncertainty as either a danger or an opportunity. Unlike the original theory, the reconceptualized model recognizes that when the outcome is negative, such as decline of a relative, appraisal of uncertainty as negative versus positive can change over time.[27] In a study applying the RUIT to dementia caregiving, uncertainty was seen to impact the appraisal of primary stressors,[29] making it conceptually consistent with other mediators. Mindfulness has been associated with cognitive flexibility, a related construct.[30] Accordingly, in our proposed intervention, we hypothesize that mindfulness training could enhance the CG's shift from a resistance to uncertainty to an acceptance of it as a natural part of life. Similarly, mindfulness

training can shift emotion regulation strategies from negative (e.g., self-blame) to positive (e.g., planning). Additionally, the proposed focus on improving family conflict should affect perceived social support, another mediator of health outcomes, thereby leading to greater self-efficacy and positive emotions.

Mindfulness-based Stress Reduction for reducing burden in dementia caregivers. Mindfulness meditation has been described as "a behavioral technique involving the intentional self-regulation of attention to present-moment experience, combined with release of cognitive fixation on thoughts (whether simple images or complex storylines) regarding the past or future."[31,32] Through training in mindfulness, individuals learn to evoke and sustain a non-judgmental state of present-moment awareness.[31,33] Research has shown that mindfulness training programs such as Mindfulness-based Stress Reduction (MBSR), which also incorporate exercises to generate compassion for oneself and others, result in reduced stress, improved coping, and a host of improved physical and psychological health outcomes.[34,35] Mindfulness training programs have been adapted and successfully utilized for a wide range of conditions, populations, and cultures including in AAs and in CGs.[36–38] Studies with AAs have shown mindfulness training to be culturally acceptable and feasible.[39] Studies with CGs, including informal CGs of persons with dementia, have shown that mindfulness interventions can decrease CG burden and improve coping skills, including decreased emotion-based coping and increased tolerance for uncertainty, as well as improve psychological well-being and quality of life.[38,40] Two studies have also shown mindfulness to improve relationship quality and communication.[41,42]

In order to increase geographic accessibility, mindfulness training programs have been successfully adapted to distance-based formats, particularly involving use of the internet[43,44] and occasionally have incorporated smart-phone or telephone-delivered mindfulness training formats.[45–48] An additional advantage of distance-based formats for CGs is their flexibility in terms of the CG's often restricted and demanding lifestyle. For rural caregivers, a telephone-delivered mindfulness program would seem to be particularly accessible, useable, and feasible, overcoming both distance and infrastructure barriers. Moreover, such a program would easily lend itself to facilitating communication between CG family members, including those who are geographically distant, thereby increasing our intervention's reach.

Developing a Telephone-Delivered Mindfulness Training Intervention (TMT) for Care Teams. In light of the above findings, and relying on Dr. Gaylord's extensive experience in adapting mindfulness-training programs and Dr. Williams' extensive experience working with African American caregivers, we plan to implement a telephone-delivered mindfulness training intervention that will incorporate:

1) Training for primary caregivers (CG) and their caregiving partner (CP) in an 8-week, telephone-based, mindfulness-based stress reduction (MBSR) program, which places additional emphasis on training in the following:
    a. mindful experiencing, including mindfulness of feelings and body sensations as

well as thoughts and emotions;
b. mindful communication, including non-verbal mindfulness, mindful listening, and mindful speaking; and
c. mindful compassion for self and others.

2) Groups of up to eight participants (four CG-CP pairs) plus an instructor, on a shared telephone line; and

Additionally, homework assignments for CG will involve listening to exercise recordings via a dial-in telephone line or computer tablet and assignments for CG-CP dyads (e.g. mindful listening and communication practices) as well as CG mindfulness practices in the presence of CRs (e.g. mindful eating, and mindful listening). Based on theory and evidence from previous mindfulness studies, we believe that this intervention holds promise of making a significant impact on reducing burden in AA rural CGs.

The study pilots a telephone-delivered mindfulness-training intervention (TMT) for caregiving teams (rather than in-person or web-based) aimed at reducing caregiver burden. Our rationale is that members of rural communities are less likely to have access to the internet, but have high likelihood of some form of telephone service, and are limited by caregiving responsibilities in their ability to attend training programs. Currently, the intervention is planned for eight weekly, one-hour telephone sessions along with one 1.5-hour retreat. Adjustments to the format are possible, based on input from key informants and the Advisory Council.

In pre-post studies, mindfulness training in pre-post studies has shown a moderate positive effect on clinical outcomes such as depression, anxiety, and physical conditions with a Hedge's g of 0.57 (95% CI 0.5, 0.64).[35] A meta-analysis of studies of mindfulness training for caregivers showed consistently positive effects on psychological outcomes.[38]

Adverse events are rarely reported in mindfulness training studies. However, the training prompts participants to attend to emotions, thoughts, and physical sensations, some of which may be unpleasant. Hence, emotional discomfort or distress (EDD) may arise for some participants. Usually, EDD resolves quickly with guidance from an experienced instructor and, as participants become more skilled in mindfulness, they recover from EDD more quickly. Mindfulness training has the potential to exacerbate dissociation in susceptible individuals—therefore, it is important to exclude such individuals unless the program is monitored by an experienced mental health clinician.

3 STUDY DESIGN

The proposed study utilizes a single-group, uncontrolled design to assess the feasibility and acceptability of telephone-delivered mindfulness training designed to alleviate caregiver burden for rural caregivers of African American individuals with moderate to severe dementia. A care partner—the person who provides additional help —is included in the intervention. The primary outcome is feasibility of the telephone-delivered mindfulness intervention as assessed by an 85% retention rate with completion of at least 6 of the intervention sessions. Pre- and post-participation interviews will assess acceptability. A diagram of the intervention and assessment plan is provided in Figure 2.

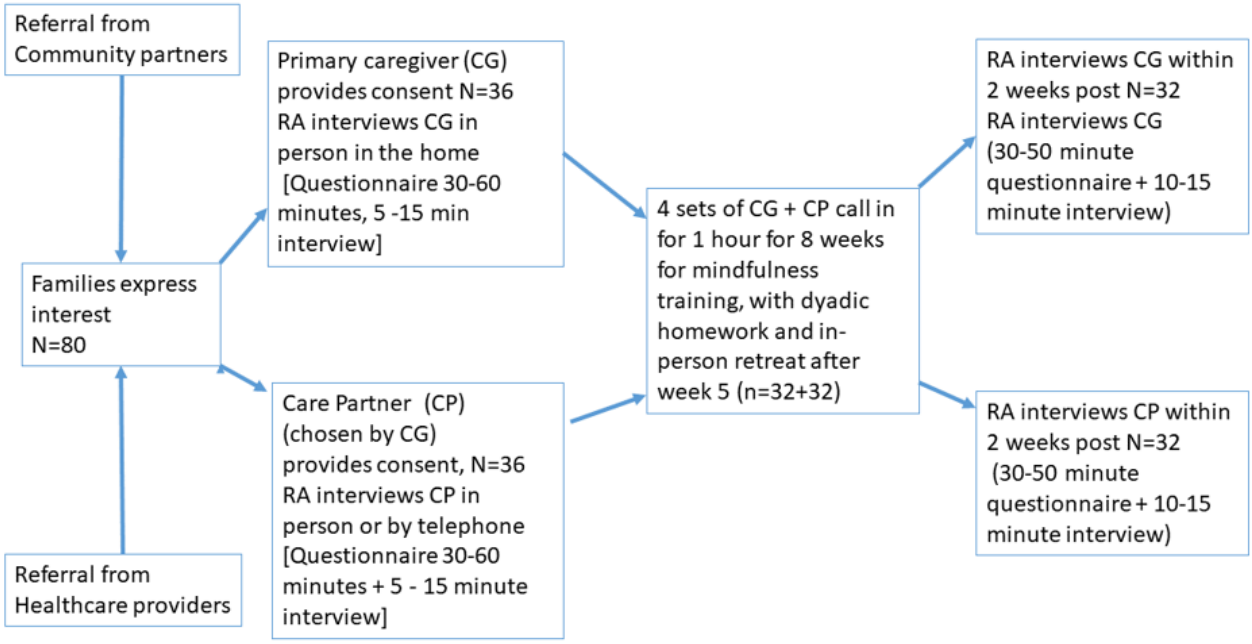

Figure 2. Intervention design*

*In-person assessments and retreat were changed in March 2020 due to COVID pandemic

SPECIFIC AIM 1: To determine the feasibility and acceptability of a telephone-delivered mindfulness training intervention (TMT) in decreasing caregiver burden among informal caregiving teams caring for African Americans with dementia.
The primary outcomes are feasibility and acceptability among primary caregivers and also among care partners.

SPECIFIC AIM 2: To explore, on a preliminary basis, the effects of the training on caregiver burden and relevant secondary outcomes for both caregiving team members. Secondary outcomes include the following:

1. Pre-post intervention differences in caregiver burden (Zarit Burden Interview);
2. Pre-post intervention differences in coping emotion regulation and coping styles (Cognitive Emotion Regulation Questionnaire);
3. Pre-post intervention differences in tolerance of uncertainty (Intolerance of Uncertainty Scale);
4. Pre-post intervention differences in anger, anxiety, and global self-perceived health (PROMIS short forms);
5. Pre-post intervention differences in family satisfaction (Family Satisfaction Scale), perceived social support among the caregivers (PROMIS Social Support short forms) and family conflict around caregiving (Family Conflict Scale);
6. Pre-post intervention differences in caregiver self-efficacy;
7. Pre-post intervention differences in mindfulness (CAMS-R scale), hopefulness, and optimism (Meaning and Purpose Scale).

SPECIFIC AIM 3: To explore comfort with and willingness to adopt technologies (e.g. telephone-based, web-based) to access mindfulness practices and existing caregiving educational resources.

1. In interviews with both the primary caregivers and the care partners, we will investigate comfort and experience with internet devices, including smartphones, tablets, and computers. For half of the intervention groups, we will ask these questions in post-participation interviews, including exploring how individuals are currently using or would like to use these technologies (e.g., voice activation, use of bookmarks).
2. For half of the intervention groups, we will ask questions about technology before the intervention and will offer each family a tablet loaded with intervention materials, including the contents of the participant binder. Post-participation interviews will include questions about the ease of use and perceived value of the tablets.

The study population will consist of 32 caregivers (CG) of African Americans care recipients (CR) with a cognitive or memory problem severe enough to prevent them from caring for themselves without assistance. Because African Americans with Alzheimer's disease and related dementias (ADRD) are less likely to have a formal diagnosis and because a formal diagnosis would not impact the potential value of the intervention for the caregiver, the study does not require a formal diagnosis. Instead, the study will require a level of disability as perceived by the caregiver to be at least moderate (see Inclusion Criteria). The study population also includes the 32 additional caregivers, care partners (CP) identified by the primary caregiver as informal team members who provide assistance. No control group is planned.

Additional participants in the study will include approximately 10 key informants from the community who will provide context, advice on cultural relevance, and advice on intervention language. These individuals may consist of informal caregivers, former caregivers, members of the Council on Aging, members of African American sororities affiliated with the Alzheimer's Association of Eastern North Carolina, or African American formal caregivers affiliated with hospitals in Eastern North Carolina.

Primary caregivers will come from Lenoir County, Wayne County, and surrounding counties in rural Eastern North Carolina. Caregiver assessments will take place in the home, or another location of the caregiver's choice. (During and following the COVID pandemic, this assessment will take place via telephone for all participants.) Care partners are not restricted geographically. Assessments of Care Partners will take place by telephone (or in a separate room in the home if they are present).

The research team will work with the individuals and organizations including the Alzheimer's Association of Eastern North Carolina (AAENC), the Study Physician, Research Fellows, and local pastors to develop a handbook of relevant caregiving resources for families (available both as a hard copy and, in half of the groups, electronically) as well as mindfulness exercises. Included in the handbook will be information about additional training for addressing CR behavioral problems (e.g., WeCare Advisor), training not covered explicitly by the proposed intervention.

The total duration of participation includes: 1) a pre-participation assessment up to 6 weeks prior to the intervention; 2) eight weeks of intervention calls plus retreat; and 3) a post-participation interview and assessment within four weeks of the last intervention call. Interventions will take place over the telephone for the 8 mindfulness training sessions. The retreat, occurring between sessions 5 and 6, will take place either at a community location convenient to the majority of the group participants, or online via Zoom, during and after the COVID.. Please see Table 1 and the intervention handbook for details of the intervention.

Table 1: Proposed curriculum for telephone-delivered mindfulness training

Session	Topics	Caregiver/Care Partner Home Assignments
1	Introductions; what is mindfulness? Relevance to caregiving; Mindful relaxation breath and Mindfulness of sound	Practice mindful relaxation breath 3-5 minutes each day. Discuss your experiences with one another (CG-CP dyad).
2	Stress: How mindfulness can help us cope; Sitting meditation and mindful walking	Practice sitting meditation for 5 minutes once daily. Discuss your experiences with one another (CG-CP dyad).
3	Being and Doing Mind; Body scan and Mindful eating	Practice Body scan +/- mindful eating. Discuss your experiences with one another (CG-CP dyad).
4	Approaching Daily Life with Mindful Awareness; Breathing space/Mindful listening	Practice breathing space daily. Practice Mindful listening techniques in CG-CP dyad.
5	Mindfulness and Self-Care; instruction in self-compassion	Practice techniques learned. Continue to practice mindful listening in CG-CP dyad. Begin a self-compassion journal.
Retreat	Mindful communication: Listening, speaking, difficult conversations	(no homework but participants are encouraged to reflect upon the day and discuss with one another)
6	Mindfulness and Resilience; Compassion for the difficult person	Practice techniques learned. Practice mindful listening and speaking and explore compassion practice in CG-CP dyad.
7	Gratitude: Appreciating the Journey; learning to express our appreciation and gratitude to self and others	Practice techniques learned for 10 minutes twice daily. Practice mindful speaking and listening dyad, focusing on gratitude for others. Reflect on and discuss what techniques you found useful and may wish to continue.
8	Mindfulness and Meaning in Everyday Life—the Journey continues	

4 SELECTION AND ENROLLMENT OF PARTICIPANTS

4.1 Inclusion and Exclusion Criteria

Informal caregiving teams will be composed of a primary and secondary informal caregiver, as defined as:

any relative, partner, friend or neighbor who has a significant personal relationship with, and provides a broad range of assistance for, an older person or an adult with a chronic or disabling condition [in this case, Alzheimer's Disease or a related dementia]. These individuals may be primary or secondary caregivers and live with, or separately from, the person receiving care. (Family Caregiver Alliance, www.caregiver.org)

The primary caregiver (CG) are adults who must:

- Care for a family member with dementia who identifies as Black or African American
    - Defined: Care recipient must have a diagnosis of dementia (reported by caregiver) or have a score of at 2 or higher on the AD-8 or a score of 8 or higher on the Functional Activities Questionnaire (FAQ).
- Provide regular, daily care (at least 4 hours per day) for a family member who has dementia
- Have another adult care partner (CP) who is willing to participate; someone who shares caregiving or helps make decisions regarding the person with dementia or Alzheimer's disease (may be remote and family member or friend)
- Have a telephone and be willing to participate in weekly calls
- Live in rural areas in Eastern North Carolina.
    - Defined: Eastern is defined as east of Wake County NC; rural is defined as listed as rural within the website https://www.ruralhealthinfo.org/am-i-rural

The primary caregiver is excluded if they:

- Are receiving active treatment for cancer
- Have been hospitalized 3 or more times in the last year

The care partner is eligible if they are 18 or older, have a telephone and are willing to attend weekly sessions. Care partners do not need to be living in the same geographic region as the primary caregiver.

4.2 Study Enrollment Procedures

Community involvement. Because little research has investigated dementia caregiver needs in eastern NC, our team proposes adjunctive qualitative methods. To assist in adapting the mindfulness-training intervention components and the handbook, we plan to conduct key informant interviews. Key informants will include local pastors, members of African American sororities affiliated with the AAENC, and members of the local Council on Aging. Additionally, we will plan interviews with African American caregivers of people with dementia

Advisory Council. We will also recruit an Advisory Council of 5-8 individuals. We will share the results of feasibility data and qualitative analyses with the Advisory Council and utilize their input in refining improving the intervention. The Advisory Council may also review the intervention manual and study logistics and provide recommendations.

Recruitment, screening and consent. We plan to recruit participants in conjunction with local service providers and community organizations in Eastern NC Counties, including AAENC and local pastors. These counties are chosen for their high AA populations (>30%) and existing relationships with UNC researchers. Should recruitment from these counties be insufficient, we will extend the intervention to neighboring rural Eastern NC counties (e.g., Duplin, Sampson).

Recruitment partners (AAAENC, affiliated sororities, pastors, Council on Aging) will advertise the study to their membership. We will have a study website where potentially interested people can indicate interest. We will also provide study flyers to the UNC Hospitals clinics in Eastern NC counties and participate in local fairs and church-sponsored events in the counties. Once COVID pandemic occurred, we also relied on Facebook ads, radio/newspaper ads, NC Brain Registry and Duke family Caregiver Support e-news, and 'snowballing' (referrals from past participants). Interested individuals may contact the study directly or may provide permission to recruitment partners for the study staff to contact them. Recruitment partners may forward contact information to study staff.

After we identify individuals, we will provide details of the intervention and screen CGs over the telephone and pre-screen individuals with a telephone consent. We will visit CGs who meet the eligibility criteria in their homes to obtain a formal written consent for participation and to administer the baseline measures. (During COVID, these procedures will be conducted completely over the phone, with verbal consent process and phone assessments. In addition, staff will obtain a verbal consent addendum to allow unencrypted texting and emailing for the main purpose of study activities reminders.) At that time, we will provide a binder with local and downloaded caregiver resources as well as mindfulness activity instructions. Participants may also access audio files with recorded mindfulness activities. In the second half of the program, participants will receive a tablet loaded with all of the contents of the binder as well as bookmarked links to ADRD information sites.

The primary caregiver will be asked to invite a care partner to participate in the study and will obtain that person's permission for us to contact them. Once permission is confirmed with the caregiver, study staff will contact the potential care partner, describe the study, and obtain verbal consent to proceed with assessments (and unencrypted messaging) as well as an invitation to participate in the intervention.

5 STUDY INTERVENTIONS

5.1 Interventions, Administration, and Duration

The study intervention is the mindfulness training for caregivers and care partners. The mindfulness training is offered in 8 weekly telephone sessions plus one weekend retreat. Respite care for the care recipient is provided for the retreat if needed.

5.2 Handling of Study Interventions

Each participant will receive a resources handbook (binder) containing the following:

- Descriptions of each class section and suggested homework exercises;
- Detailed descriptions of mindfulness practices taught in the class;
- Instructions for how to access recorded mindfulness practices;
- A list of community resources for individuals with ADRD and their caregivers, including contact information;
- A list of national resources for individuals with ADRD and their caregivers;
- Instructions for caregivers based on material published by the researchers (Lathren, Kaufer);
- Select downloaded materials from the Alzheimer's Association of Eastern NC and other relevant websites.

Half of the groups will receive an electronic tablet loaded with the handbook, recordings, and links to resources bookmarked. We will program voice-enabled personal assistants on the tablet to enable access to bookmarked resources. We will investigate the best way to provide internet service for each participating family for at least 4 months (e.g., cell, DSL, cable). During the baseline (in-home) visit, we will teach CGs how to use the handbook. CGs who receive the tablet will also learn how to use it in the baseline visit. In follow-up interviews, we will ask to what extent CGs used the handbook, tablet (if relevant), and call-in lines. Given it is unclear if and how technologies will be used in this population, this aspect of the study will provide insight on which components of the intervention will be most useful to include in future iterations. Because half of the groups will receive the tablets, we will be able to examine the difference in adherence and engagement between groups with the tablets and without the tablets.

For the intervention, each trained, experienced mindfulness instructor will work from an instructor's manual prepared by Dr. Gaylord. The instructor's manual, designed for experienced mindfulness instructors, will detail the intervention components, providing tips on teaching the material and responding to participant questions. Consultant Mary Brantley, an expert in telephone-delivered mindfulness, will review and edit the instructor's manual.

5.3.1 Allowed Interventions

Caregivers and care partners are not restricted from participating in any care recommended by their physicians. We ask that they delay additional mindfulness-based therapies until after the end of the intervention.

5.3.2 Required Interventions

No interventions are required outside of the mindfulness training intervention with the accompanying handbook (on paper alone or on paper plus a tablet).

5.3.3 Prohibited Interventions

No interventions are prohibited, but we will ask participants to delay engaging in mindful yoga or mindfulness-based therapy until after the intervention, if possible.

5.3 Adherence Assessment

Adherence is assessed via a class participation log kept by the instructor as well as a data-

tracking website kept up by the project manager and her staff. The tracking website documents attendance at class sessions, instructions for participants outside of class sessions (if sessions are missed), and completion of study assessments.
Acceptance of the treatment and control programs as measured by attendance at ≥ 6 intervention sessions.

6 STUDY PROCEDURES

Table 2 outlines the schedule of evaluations for participants during their study participation.

Table 2: Schedule of Evaluations

Assessment	Telephone Screening: (≤5 Wks prior to enrollment)	Baseline, Enrollment: Visit 1 (W-4 to W0)	Telephone sessions Visits 2-6 (W1 to W5)	Retreat Visit 7 (W5.5)	Telephone sessions Visits 8-10 (W6 to W8)	Follow-up: Final Visit (by W15)
Screening consent	X					
Preliminary review of eligibility	X					
Demographics	X					
Informed Consent		X				
Inclusion/Exclusion Criteria		X				X
Enrollment		X				
Baseline interview		X				X
Baseline questionnaires (by interview or paper for CG; by interview or online for CP)		X				
Attendance			X	X	X	
Homework assessments			X		X	
Post-participation interview						X
Follow-up questionnaires (by interview or paper for CG) (by interview or online for CP)						X
Adverse Event assessment			X		X	X

6.1 Description of Evaluations

6.1.1. Screening Evaluation

These evaluations occur to determine if the candidate is eligible for the study.

Consenting Procedure

Prior to enrollment, interested caregivers will have an opportunity to hear more details about the study. If they continue to be interested, they will provide a telephone consent for review of eligibility and collection of demographic information. If they are eligible and wish to participate in the intervention, study staff (research assistant and/or project manager) will make an appointment for a home visit for enrollment and baseline assessments of the caregiver and/or care partner (during/post-COVID, this changed to a phone appointment). At that time, study procedures will be reviewed again and the caregiver will provide written informed consent (verbal consent and consent addendum for unencrypted messaging post-COVID).

The caregiver will identify a care partner and, with their permission, provide contact information to the study staff. Because care partners may live in a distant geographic location, their consent may be obtained by verbal consent over the telephone. Screening and consenting can take place at the same time or in two different calls, at the discretion of the care partner.

If changes are made in the study that affect the risk of the intervention before completion of their part of the study, study staff will contact participants again to review a revised consent. Participants who have completed the study will receive a letter explaining the increased risks.

Physical, signed consent documents are stored in a consent binder, to be locked in a portable file cabinet. Study staff will upload the consent documents into the study REDCap site. At intervals, study staff will transport the consent forms and all paper assessments to the project manager to be locked in a file cabinet controlled by the PIs. Once verbal consent processes are in place, verbal consent will be documented on consent forms by the research staff obtaining consent, and stored using TEAMS.

Screening

Caregivers must be screened within 5 weeks of the baseline assessment. It is anticipated that class sessions will begin within four weeks of baseline assessments for each caregiver and care partner.

- At the time of the screening call, the caregiver will verify that they provide at least 4 hours of care per day to the care recipient.
- The caregiver will also verify that they have a family member or friend who assists with care and who is likely to be agreeable to participation in the telephone mindfulness sessions.

- At the time of the baseline visit, the eligibility criteria will be reviewed and completed via an inclusion/exclusion checklist.
- The caregiver will obtain permission for contact from the care partner and give this information to the study staff.

6.1.2. Enrollment, Baseline, and/or Randomization

Enrollment

The first enrollment date is defined as the date that the primary caregiver reviews and signs the written informed consent document. A primary caregiver may still choose to withdraw from the intervention prior to the first intervention session. The primary caregiver will become ineligible for the first intervention session if a care partner does not agree to participate. Hence, a second definition of enrollment, akin to the point of randomization, is the date of the first intervention session. Each individual who participates in the first class session will be considered to be a participant in the intervention. The date of enrollment (baseline assessment) and attendance at the first class session are recorded in the secure study database, REDCap.

Baseline Assessments

At baseline, the caregiver will participate in a pre-participation interview, lasting 10-15 minutes. The purpose of the interview is to assess, qualitatively, the caregiver's knowledge about mindfulness or centering prayer, perceived value of telephone-based group classes, and comfort with technology.

Table 3: Questionnaire assessments

Measure (construct)	Reliability, validity
Outcome: Zarit Burden Interview (ZBI) (distress associated with caregiving)[49]	This 12-item (SF) version of the popular original 29-item questionnaire measures role strain (α=0.88) and personal strain (α=0.77) The short form was highly correlated with the original (0.96) both at baseline and follow-up.
Outcome and secondary stressor: Family Conflict Scale (Negative family interactions around caregiving)[22]	The 4-item Family Conflict scale measures the degree of conflict the family experiences about the seriousness of the CR's condition, concerns about the CR's safety, what the CR can do for him/herself, and whether a nursing home is indicated.
Mediating outcome: Cognitive emotion regulation questionnaire (coping styles)[50]	The 18-item short form of the CERQ measures 5 positive coping strategies (acceptance, positive refocusing, planning, positive reappraisal, putting into perspective) and 4 negative strategies (rumination, catastrophizing, self-blame, other-blame). Subscale reliability (α=0.68-0.81) and convergent validity was good.
Mediating outcome: Intolerance of Uncertainty Scale (discomfort with uncertainty)[51]	The12-item IUS correlates highly (0.96) with the original 27-item scale and results in a 2-factor (prospective, inhibitory) scale. Item responses range from 1(*not at all characteristic of me*) to 5 (*entirely characteristic of me).* Its reliability was high for both the overall score (ρ=0.92) and subscales and it demonstrated convergent validity.[52] We will contact the scale developers to obtain permission

	to adjust to language of the responses to accommodate individuals without a high school education.
Mediating outcome: PROMIS social support measures (emotional, informational, instrumental support)	All three 4-item social support scales assess the frequency of perceived support with responses ranging from *1 (Never) to 5 (Always)*. Scoring is implemented in REDCap to preserve response pattern metrics.
Outcome: PROMIS self-efficacy: general [4], and emotion management self-efficacy [4][53]	PROMIS investigators created population-standardized scales with improved reliability, validity, and precision.[54] In 1,087 patients, self-efficacy measures were correlated with other self-report measures as expected.[53] We will be using the 4-item general self-efficacy short form as well as the 4-item short form for self-efficacy of emotion management.
Outcome: PROMIS Emotional Distress (anxiety and anger) [55]	The 4-item anxiety short form and 5-item anger short form are measured across the past 7 days with responses ranging from 1 (*Never*) to 5 (*Always*). In MDD, CHF, and back pain patients, the measures were responsive to change with treatment.
Outcome: PROMIS global physical health (Self-rated health)[56]	The global health measure is based on the well-validated RAND measure, assessing general self-rated physical health, physical function, pain, and fatigue. The 4-item scale has a marginal reliability of 0.81.
Process measure: Cognitive and Affective Mindfulness Scale-Revised	This is a 12-item scale measuring mindfulness that uses a 4-pont Likert scale with responses ranging from 1 (Rarely/Not at all) to 4 (Almost always). Scores range from 12-48. Higher scores indicate higher levels of mindfulness.
Process measure: Family Satisfaction Scale (perceived cohesion, flexibility, communication)[59]	The 10-item Family Satisfaction Scale has been tested in a variety of populations. In a sample of 2,465, the mean was 37.5 with SD of 8.5. The 10-item scales has test retest reliability of 0.85 and alpha of 0.92. Convergent validity was demonstrated in survivors of TBI[60]
Potential Moderator: Neuropsychiatric Inventory (caregiver distress associated with neuropsychiatric symptoms)[61,62]	The NPI measures the severity of 12 symptoms in a patient with dementia (e.g., delusions, anxiety, appetite change) along with the caregiver's distress regarding symptoms (0-*Not distressing at all*; 5-*Extreme*).
Potential Moderator: Functional Assessment Staging of Alzheimer's disease[63–65]	The caregiver assesses the stage of AD based on clearly defined descriptions corresponding to deficits in IADLs and ADLs. The scale has high inter-rater reliability and convergent validity. This is a single question.
Outcome: PROMIS Meaning and Purpose (hopefulness and optimism)	The 7-item meaning and purpose scale is a reliable, validated population-normed well-being measure developed to assess positive emotions.
Potential Moderator: Demographics	Age, sex, marital status, education, employment status, income, relationship to CR, duration of dementia caregiving

The caregiver will also complete questionnaires**.** The primary way these questionnaires

will be completed is via interview with study staff over the phone. If they prefer, they may complete the questionnaires on paper, or via a secure REDCap link, with assistance from study staff as needed. Questionnaire assessments are provided in Table 3. It is anticipated that the questionnaires will take up to an hour to complete.

The care partner will have the choice of completing the baseline questionnaires with the study staff over the phone or to complete the measures online using the REDCap survey interface (which can also be configured to read the questions to participants).

Randomization
Not applicable

6.1.3. Follow-up Visits

- Visits 2-6 (Week 2 – Week 5):
  (Telephone class sessions may be delayed by one week for unavoidable circumstances, e.g., instructor illness, inclement weather)
  - The instructor will submit information on intervention attendance weekly
  - Study staff will call participants to inquire about practice and adverse events at least once during this period

- Visit 7 (Week 5.5)
  Retreat may be delayed by one week for unavoidable circumstances, e.g., instructor illness, inclement weather
  - The instructor will submit information on intervention attendance

- Visits 8-10 (Week 6 – Week 8)
  Telephone class sessions may be delayed by one week for unavoidable circumstances, e.g., instructor illness, inclement weather
  - The instructor will submit information on intervention attendance weekly
  - Study staff will call participants to inquire about practice and adverse events at least once during this period

6.1.4. Completion/Final Evaluation

Study staff will make an appointment with the primary caregiver to complete assessments within 4 weeks of the last telephone class session, regardless of how many sessions the caregiver attended. With the research assistant, the caregiver will complete the following assessments:

- Post-participation interviews will address the caregiver's attitudes and experiences with the program, including:
  - most memorable aspects of program;
  - perceived value and cultural congruence of the mindfulness training;

- usefulness, challenges, and recommended changes;
- perceived value for management of stress related to caregiving or family conflict;
- tools that might help maintain practices;
- unfulfilled expectations of the program;
- usefulness of the technology components (e.g., call-in lines, tablets), if relevant.

Study staff will complete a similar interview with the care partner over the telephone. With permission of the participants, each interview will be audio-recorded and transcribed.

- Questionnaires to be completed with the caregiver and care partner at the final visit include all previously administered outcome measures.

If participants withdraw before the end of the intervention, study staff will ask them to complete the interview and questionnaires associated with the final visit, if possible, either in person or over the telephone. Study staff will also inquire about adverse events that may have led to discontinuation.

7 SAFETY ASSESSMENTS

The risks leading to adverse experiences for participants enrolled in the study are minimal, but do exist. Potential adverse experiences for participants as a result of the telephone-delivered mindfulness intervention include:

- Emotional or psychological discomfort or distress, including:
  - Avoidance
  - Agitation
  - Anxiety
  - Difficulty focusing
  - Irritability
  - Nervousness
  - Obsessive thoughts
  - Panic
  - Restlessness
- Physical symptoms associated with emotional/psychological discomfort or distress:
  - Body or joint aches (resulting from intervention practices)
  - Headaches (resulting from intervention practices)
  - Heavy sweating (without performing strenuous activity)
  - Hyperventilation or rapid breathing (without performing strenuous activity)
  - Nausea or gastrointestinal problems (outside of sickness)
  - Rapid heart rate (without performing strenuous activity)

Study staff will encourage participants that they do not have to answer any questions that make

them feel uncomfortable on study questionnaires. During intervention sessions, participants will be encouraged to participate, but can choose not to do an activity that makes them feel uncomfortable. Study staff and the intervention instructor will make participants aware of the experiences that can occur prior and during their time in the study. Study staff will encourage participants to report emotional distress/discomfort and physical symptoms during intervention sessions and through follow-up calls with study staff, which will occur up to 3 times during the intervention. Adverse events will be captured using the Periodic Telephone Administered Adverse Event Monitoring Form.

7.1 Specification of Safety Parameters

Measures used to assess safety for participants include periodic telephone check-in with participants. In the check-in, study staff query participants regarding both psychological and physical health. Any event that does not clearly meet the criteria for a mild AE will be investigated by the designated principal investigator and Study Physician (medical officer). The PIs with the Study Physician will determine the severity of the AE, relatedness to the study, and recommended follow-up. Follow-up will include providing the participants with a list of resources and, in more acute cases, recommendations to see their primary care provider.

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

Timing for assessing, recording, and analyzing safety and adverse events will be completed in the following ways:

- **Assessing**: instructors will prompt the study staff to follow-up with any participants that is endorsing emotional or physical difficulties during the telephone sessions to further assess for adverse experiences.

  Study staff will contact participants up to 3 times during the intervention to complete the Periodic Telephone Administered Adverse Event Monitoring Form to assess for safety and adverse events (see Supplementary Materials).

- **Recording:** study staff will document safety and adverse events in the Adverse Event Reporting Form (See Supplementary Materials).

- **Analyzing:** all safety and adverse events will be reviewed by the PI, or a designee to assess the severity and level of follow-up needed for each participant. Moderate and severe level AEs will also be reviewed by the Study Physician, as needed. All reported events will be reported to the Safety Monitoring Committee and IRB for review twice a year and annually, respectively. SAEs will be reported to the Safety Monitoring Committee and IRB within 24 hours of the study staff receiving the report from a participant.

7.3 Adverse Events and Serious Adverse Events

The study team, led by the PIs, will monitor all participants for 3 categories of events: adverse events (AEs), serious adverse events (SAEs) and unanticipated problems (UPs). These three categories are defined as follows:

Adverse event (AE): Any unfavorable and unintended change in physical or mental health status (i.e. new or worsening physical or mental health signs, symptoms, or disease) associated with participation in the study, regardless of whether it is considered related to the study.

Serious Adverse Event (SAE): Any AE 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

Unanticipated problems (UPs) involving risks to subjects 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 IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject 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 subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

This study uses the following AE grading scale:

- Mild: An experience that is transient and requires no special treatment or intervention. The experience does not generally interfere with usual daily activities. In this study, an example includes mild emotional distress that persists after a class session has ended.

- Moderate: An experience that is alleviated with simple therapeutic treatments. The experience impacts usual daily activities. In this study, an example includes moderate emotional distress requiring counseling.

- Severe: An experience that requires therapeutic intervention. The experience interrupts usual daily activities. In this study, an example includes depressive symptoms requiring pharmacological intervention or withdraw from the study. If any hospitalization (or prolongation of hospitalization) is required for treatment, it becomes an SAE.

This study uses the following AE attribution scale:

- Not related: The AE is clearly not related to the study procedures (i.e., another cause of the event is most plausible and/or a clinically plausible temporal sequence is inconsistent with the onset of the event).
- Possibly related: An event that follows a reasonable temporal sequence from the initiation of study procedures, but that could readily have been produced by a number of other factors.
- Related: The AE is clearly related to the study procedures. This study uses the following AE expectedness scale:
    - Unexpected: nature or severity of the event is not consistent with information about the intervention in the protocol or consent form
    - Expected: event is known to be associated with the intervention under study

7.4 Reporting Procedures

All reported events will be reported to the Safety Monitoring Committee and IRB for review twice a year (after the second, fourth, sixth, and eighth groups) and annually, respectively. SAEs will be reported to the Safety Monitoring Committee and IRB within 24 hours of the study staff receiving the report from a participant.

7.5 Follow-up for Adverse Events

Any event that does not clearly meet the criteria for a mild AE will be investigated by the designated principal investigator and Study Physician (medical officer). The PI and/or Study Physician will determine the severity of the AE, relatedness to the study, and recommended follow-up. Follow-up will include providing the participants with a list of resources (also available in the study handbook provided at enrollment). Participants may be advised to see their primary care provider. Study staff will check in with the participant weekly to ascertain resolution of the AE.

7.6 Safety Monitoring

Study staff will collect data on AEs and UPs on an ongoing basis from study start to study completion.

General AE Procedures. The project manager or study staff will report all AEs to the PIs monthly using the Adverse Event Reporting Form, after having gathered all necessary details. Study staff will report AEs that are more than mild and possibly related to study participation to the PIs right away. Together the PIs will determine the severity and the relatedness of the AE, and will confer with the SMC and the Study Physician, Dr. Jessica Barnhill, as needed. If the AE is serious and/or unexpected, possibly related to study participation, and suggests increased risk for participants, the procedures outlined below will also be followed.

AE reports will be collected by the project manager or study staff, summarized and de-identified. A summary report of all AEs to date will be sent to the PIs at each monthly full-team meeting.

All AEs will be summarized as part of the Data and Safety Monitoring Report submitted subsequent to the second, fourth, sixth, and eighth 8-week sessions to the SMC and NIA program officer. As per UNC IRB guidelines, all AEs will be reported to the UNC IRB during the yearly study review process.

Serious AE Procedures. The project manager or study staff will report all SAEs to the PI immediately using the Adverse Event Reporting Form, after having gathered all necessary details. For all deaths and for any SAE related or possibly related to study participation, the PI will send this report and any additional information, including corrective actions already taken, within 24 hours to the SMC chair, UNC IRB and NIA program officer. The PI will follow any additional course of action recommended by the UNC IRB, NIA, and/or SMC. All other SAEs (not unanticipated or related) will be summarized and reported to the SMC and the NIA Program Officer quarterly.

Unexpected and Related AEs/UPs with increased risk. All AEs that are deemed 1) unexpected; 2) possibly or probably related to study participation; and 3) suggests increased risk for study participants will be reported to the UNC IRB, NIA project officer, and the SMC chair within 48 hours of study team awareness of the event, using each organizations' respective reporting formats. In these reports, the PI will identify any corrective action planned or already undertaken. The PI will follow any additional course of action recommended by the UNC IRB, NIA, and/or SMC.

The SMC will meet in person (or virtually for long-distance members as needed) at least 4 times throughout the study to review the Data and Safety Monitoring Report: 1) prior to first enrollment; 2) after the first 2 cohorts (2 8-week sessions); 3) after 6 cohorts have completed (6 8-week sessions); 4) at study completion (8 8-week sessions).

Additional meetings (ad-hoc) will occur as requested by the PI for review of unexpected adverse events or any SAEs that occur. Any recommended changes by the SMC will be submitted to the UNC IRB for approval.

7.7 Emergency situations

Given participation is completely virtual, for any potential emergency situation that occurs while on the phone with participants, the study staff will ask the participant to call 911 or their physician as needed. Permission will be obtained at study outset (consent) to contact an emergency contact as needed. The study physician and key staff will also be informed ASAP, and an AE form will be recorded. (Emergency numbers are listed in TEAMS.)

8 INTERVENTION DISCONTINUATION

8.1 Discontinuation of Intervention for a Participant

Participants will be discontinued if adverse events cause:

- Cognitive impairment that prevents participant's understanding or ability to comply with study requirements; or
- Emotional distress that results in psychosis or hospitalization for psychological trauma.

In these situations, study staff will continue to follow-up until participants are under the care of their provider.

Participants may voluntarily withdraw their participation in the study at any time and for any reason. We anticipate that the family care team may wish to withdraw at the time of the death of the care recipient. Participants will continue to be followed, with their permission, even if withdrawal occurs prior to all study activities being completed. All participants that withdraw early, but continue to be followed, will receive follow-up calls to complete the *Telephone Administered Adverse Event Monitoring Form*. Participants will be asked to complete the Final Evaluation for the study (see Section 6.1.4) at the same time point of those in their cohort. If participants withdraws prior to completing all study activities and refuses to be followed, they will be instructed to connect with their primary care provider for any unresolved adverse events and asked to complete the Final Evaluation for the study (see Section 6.1.4) at the time of withdrawing from the study.

If the withdrawal rate is higher than anticipated (see Section 9.3), additional cohorts may be recruited to reach an adequate sample size.

9 STATISTICAL CONSIDERATIONS

9.1 General Design Issues

Hypotheses related to the study are provided in this protocol. A single-arm, pre-post design will assess the primary outcomes of feasibility and acceptability. Eight weekly intervention sessions with a retreat is considered the minimum amount of time needed to deliver all components of the intervention. Please see Table 3 for reliability and validity information for each of the scales.

SPECIFIC AIM 1: To determine the feasibility and acceptability of a telephone-delivered mindfulness training intervention (TMT) in decreasing caregiver burden among rural, African American, informal caregiving teams of people with dementia.

Hypothesis 1: TMT will be feasible within the rural, African American, informal caregiving teams. Feasibility is established when 85% (95% CI: 72.5, 97.5) of participants in the telephone-delivered mindfulness training intervention complete at least six sessions of the intervention.

Hypothesis 2: The adapted TMT will be acceptable to rural, African American, informal caregiving teams as evidenced by an 85% (95% CI: 72.5, 97.5) endorsement of the program in post-participation interviews.
SPECIFIC AIM 2: To explore, on a preliminary basis, the effects of the training on caregiver burden and relevant secondary outcomes for both caregiving team members, including:

SPECIFIC AIM 2: To explore, on a preliminary basis, the effects of the training on caregiver burden and relevant secondary outcomes for both caregiving team members, including:

Hypothesis 1: Compared with baseline levels, we hypothesize that mindfulness training will reduce caregiver burden (Zarit Burden Interview).

Hypothesis 2: Compared with baseline levels, we hypothesize that mindfulness training will improve emotion regulation by increasing positive coping styles (acceptance, positive refocusing, positive reappraisal) and decreasing negative coping styles (rumination, catastrophizing, self-blame) as measured by the Cognitive Emotion Regulation Questionnaire.

Hypothesis 3: Compared with baseline levels, we hypothesize that mindfulness training will increase tolerance of uncertainty as measured by (an adapted form of) the Intolerance of Uncertainty Scale.

Hypothesis 4: Compared with baseline levels, we hypothesize that training in mindful communication will increase perceived social support among the caregivers (PROMIS Social Support short forms).

Hypothesis 5: Compared with baseline levels, we hypothesize that training in mindful communication reduce family conflict around caregiving (Family Conflict Scale).

Hypothesis 6: Compared with baseline levels, we hypothesize that mindfulness training will reduce anger and anxiety (PROMIS scales).

Hypothesis 7: Compared with baseline levels, we hypothesize that mindfulness training increase global self-perceived physical health (PROMIS short forms).

Hypothesis 8: Compared with baseline levels, we hypothesize that mindfulness training increase meaning and purpose (PROMIS short form).

Hypothesis 9: Compared with baseline levels, we hypothesize that mindfulness training along with a caregiver resources handbook will increase caregiver general and emotional self-efficacy (PROMIS scales).

Hypothesis 10: Compared with baseline levels, we hypothesize that mindfulness training will increase family satisfaction (Family Satisfaction Scale).

Hypothesis 11: Compared with baseline levels, we hypothesize that mindfulness training will increase mindfulness (Cognitive and Affective Mindfulness Scale).

SPECIFIC AIM 3: To explore comfort with and willingness to adopt technologies (e.g. telephone-based, web-based) to access mindfulness practices and existing caregiving educational resources. As part of intervention planning, using interviews, we will investigate comfort with a smartphone/tablet. For half of the groups of participants, we will provide a tablet loaded with the handbook and all of the intervention materials. In this way we can compare engagement and program acceptability rates between groups who received the tablets and those who did not.

9.2 Sample Size and Randomization

We calculated the effect size for the feasibility outcome, the acceptability outcome, and the Zarit Burden Interview. The sample size depends on the number of individuals who can reasonably participate in a telephone mindfulness intervention and takes into consideration the challenges of recruiting study participants in rural areas among underprivileged groups. We expect that no more than 8 caregivers could participate in a call at one time. Limiting the group size to 8 will ensure that all participants have an opportunity to contribute and that the instructor can keep track of all participants.

We anticipate being able to recruit no more than 36 CG-CP dyads in two years and expect a withdrawal rate of 10-15%. We anticipate having 32 dyads join the intervention and complete all baseline assessments and that 28 of those will complete all post-participation assessments. We will make every effort to follow-up with every participant, either in person or on the telephone, resulting in little missing qualitative data. We will use multiple imputation procedures to account for missing quantitative data.

Based on a sample size of 32 and a pre-post correlation of 0.5-0.7, we will have 75-80% power to detect a pre-post difference in the ZBI means of 3.3 – 4.2 consistent with an effect size of about 0.5 utilizing and alpha of 0.05. This effect size is consistent with those reported in other mindfulness interventions. The sample size of 32 with a feasibility of 85% would result in a 95% CI of 72.5 to 97.5. Similarly, a sample size of 32 with an acceptability of 85% (based on interviews with participants) will result in a 95% CI of 72.5 to 97.5. If we have higher than anticipated withdrawal rates, we will have lower precision.

9.2.1 Treatment Assignment Procedures

This is a single-arm study. Randomization and masking do not apply.

9.3 Interim analyses and Stopping Rules

We do not plan an interim analysis. The study will be stopped if 3 or more individuals have a serious adverse event probably or definitely related to the study.

9.4 Outcomes

9.4.2 Primary outcome

1) The primary outcome is feasibility. We define feasibility as 85% of participants who start the intervention will complete at least 6 of the intervention sessions. Feasibility is measured by class session attendance records collected at the time of the calls by the instructor. The instructor will notify the project manager who attended the call and the project manager will document attendance in the REDCap database.

2) (Qualitative) A second primary outcome is acceptability. We define acceptability as 85% of participants expressing comfort with the majority of the intervention components and homework.

9.4.3 Secondary outcomes

3) Change in caregiver burden as measured with the Zarit Burden Interview;
4) Change in emotion regulation/coping styles as measured with the Cognitive Emotion Regulation Questionnaire (CERQ);
5) Change in uncertainty tolerance as measured with the Intolerance of Uncertainty Scale (IUS);
6) Change in mindfulness as measured by the CAMS-R.
7) Change in perceived social support among caregivers as measured with the PROMIS social support short forms for emotional, informational, and instrumental support;
8) Change in family conflict around caregiving as measured by the Family Conflict Scale;
9) Change in emotional distress as measured by the anger and anxiety PROMIS short forms;
10) Change in perceived health as measured by the PROMIS global health short form;
11) Change in hopefulness and optimism as measured by the PROMIS meaning and purpose short form;
12) Change in caregiver self-efficacy as measured by the PROMIS self-efficacy short forms.
13) (Qualitative) Evaluation of the comfort with and willingness to adopt technologies to access mindfulness practices and existing caregiving educational resources.

9.5 Data Analyses

This is a single-arm pilot feasibility study with one baseline and one post-intervention measure.
Quantitative variables

For all quantitative questionnaire measures (outcomes 3-11), the change in the measure from baseline to post-participation is the outcome. First, we will examine variable distributions and missing data patterns. Next, we will conduct exploratory, descriptive analyses to assess *patterns of change* associated with participation in the programs for each of the variables including proximal mediating outcomes, intermediate outcomes (secondary stressors), and distal health outcomes. Because all analyses are exploratory, we will next perform bivariate assessments utilizing a paired t-test, analyzing caregivers and care partners separately. We do

not plan to adjust for multiple comparisons, but will interpret results conservatively and with great caution.

We will also explore the use of multivariable methods to enable us to control for variables that could influence the outcomes. Adjusted models will utilize repeated measures mixed models with individuals nested in families as random effects. We will control for the baseline FAST score (severity of dementia) and the relationship to the care recipient (spouse, adult child, other relative). In this small study (32 dyads), it will not be possible to formerly assess subgroups defined by gender. However, we will produce descriptive statistics by gender and age group.

We plan to invoke an intention-to-treat analysis in dealing with missing data using multiple imputation or full information maximum likelihood methods.

Qualitative variables

We will collect three types of formal qualitative data: 1) telephone interviews with key informants; 2) interviews with CG and CP prior to and following each 8-week class; and 3) transcriptions of audio-recorded classes. See key informant topics above. We will use the insights from key informants to adjust the intervention including the content and the logistics as needed.

Pre-participation interviews will address participant expectations and concerns about the research process in general and the intervention in particular.

Post-participation interviews will address CG/CP's attitudes and experiences with the intervention, including:

- The most memorable aspects of the class sessions;
- The perceived value and cultural congruence of the mindfulness training;
- The usefulness, challenges, and recommended changes in intervention components or language;
- The perceived value of various intervention components for management of stress related to caregiving or family conflict;
- Their recommendations for tools that might help maintain practices, if desired;
- Their unfulfilled expectations of the intervention;
- The usefulness of the technology components (e.g., call-in lines and/or tablets).

Each interview will be audio-recorded and transcribed. Using transcripts of key informant interviews and post-participation interviews, two or more research team members will apply a thematic analysis strategy, coding each transcript and identifying themes within and across interviews, with subsequent discussion of themes among members of the qualitative analysis team and resolution of discrepancies. The qualitative analysis team, who will include the PIs and Dr. Roth, among others on the study team, will categorize the themes and present them to the Advisory Council for further input. Results will inform improvements in subsequent iterations of the intervention as well as the development of larger-scaled interventions.

10 DATA COLLECTION AND QUALITY ASSURANCE

10.1 Data Collection Forms

We will include data from multiple sources. For pre-post assessments with the caregiver, research assistants will collect demographic and questionnaire data on paper and input data into a secure, password-protected, web-based database for analysis. The research assistant will lock the paper case report forms in a portable filing cabinet until they can be transported to UNC for storage. The research assistant (RA) will follow a detailed Manual of Procedures for each aspect of data collection for each study visit and complete a visit checklist. On each checklist, the research assistant will document aspects of the visit that were completed, omitted (e.g., refused), and provide comments. Each checklist will be signed and dated by the RA and will become a CRF.

10.2 Data Management

The UNC Program on Integrative Medicine will be responsible for all study staff and data collection. The study research assistant will collect data in the home of the caregiver and over the telephone for the care partner. UNC utilizes the REDCap database from which the study can download validated paper case report forms that correspond to the online database. All of the PROMIS measures are already available. Measures currently unavailable will be created with the assistance of the Clinical Data Manager at the North Carolina Translational and Clinical Sciences Institute.

Program Fidelity. With the permission of all participants, all program sessions will be audio-recorded. The purpose of the recording is two-fold: 1) to identify any systematic variations in instructors' attitude, communication, or behavior between groups and to screen for any group-dependent differences in communication in content or style between the instructors and participants; and 2) to capture participants' input and comments during the classes (for qualitative analysis). We will develop an evaluation matrix based on written protocols. Dr. Gaylord will listen to each program session to rate adherence to the protocol and will discuss deviations with the instructor, who may suggest changes to the intervention based on participant feedback.

10.3 Quality Assurance

10.3.1 Training

All study staff will maintain up-to-date Good Clinical Practice, HIPAA, and Research Ethics training. Before participant data is collected, a PI or Project Manager will ensure that staff has completed training for applicable tasks. A log including dates and type of training will be kept in the Study Regulatory Binder.

The study's Manual of Operating Procedures (MOP) will include detailed procedures for each of the following:

- Consent forms:
    - Telephone/screening with detailed script and instructions included
    - Full Consent (detailed description in section 6.2 of protocol)

- HIPAA Consent

- REDcap data entry (used to track recruitment data, initial and post-intervention evaluations, study visits, and questionnaires)
- Interview techniques along with procedures for recording interview data
- Verbal and written administration of questionnaires.

10.3.2 Quality Control Committee

The Quality Control Committee will consist of the project manager, the data manager, and the PIs. They will meet monthly to review data or process problems.

10.3.3 Metrics

The data manager will audit 10% of the data entries each month in preparation for full team meetings of the study. She will identify and correct systematic errors in data entry by reviewing procedures with the research assistant. She will correct data entry errors using the original case report forms. If data entry error rates >10% persist, all data will be double entered.

10.3.4 Protocol Deviations

Staff will be trained to record any protocol deviation that may occur while performing their specific research related activities. Many of the data collection forms will include comment sections to capture protocol deviation information. The project manager will document all protocol deviations in the secure online database, REDCap, as they occur. The entire study team will discuss deviations at monthly team meetings and report them to the IRB annually. Corrective action plans will be developed and submitted to the IRB as part of the reporting process

10.3.5 Monitoring

The data manager (co-investigator) will review REDCap data for protocol compliance (including eligibility criteria) and audit data entry monthly within one month of the beginning of the first intervention group. This will include a biannual review of study instruments for range and consistency checks, and descriptive analyses to assess distributions of study variables. The project manager will review consent forms for completeness and institute remedial training for the research assistant as needed. The project manager is responsible for creating and reviewing the MOPs.

Quality assurance of qualitative measures (project manager) include 1) maintaining a database of scheduled, completed, transcribed, and analyzed classes and group evaluations; 2) establishing a transcription template to ensure data are uniform in appearance; 3) arranging for secure storage of recordings and transcripts; and 4) review of recordings to assess accuracy of transcriptions.

11 PARTICIPANT RIGHTS AND CONFIDENTIALITY

11.1 Institutional Review Board (IRB) Review

This protocol and the informed consent documents and any subsequent modifications will be reviewed and approved by the IRB and the Scientific Review Committee responsible for oversight of research at the University of North Carolina at Chapel Hill. The IRB application, modification and renewal procedures will be adhered to throughout the study.

11.2 Informed Consent Forms

Interested caregivers meeting the screening criteria for eligibility in the study will be given a copy of the informed consent form (ICF) in the presence of the research assistant. The research assistant will read the ICF to the potential participant pointing out important aspects in each section and answering any questions. The caregiver may choose to sign the ICF at that time or to make another appointment for the research assistant to return. The ICF will describe the purpose of the study, the procedures to be followed, reasons not to be in the study, the risks and benefits of participation, responsibilities of the participant, incentives and remunerations, privacy and confidentiality measures, and the names and contact information for the PI and the study staff. After the caregiver agrees to participate and signs the ICF, the research assistant will sign. If verbal consent, the staff member will indicate verbal consent was given on the consent form. A copy will be given to each caregiver and this fact will be documented in the participant's record.

Because care partners may live at some distance from the caregiver, a telephone consenting procedure will be implemented. The procedure will include all of the aspects of the written consent, but will enable interested care partners to give their verbal consent over the telephone. Each care partner will receive a copy of the ICF in the mail. Their verbal consent will be documented in their record.

11.3 Participant Confidentiality

Participant confidentiality will be maintained according to the Health Insurance Portability and Accountability Act (HIPAA). Research records arising from this study will be retained at a secure UNC-maintained locked site for 15 years with access limited to the PI and named designees.

Any data, forms, reports, and other records that leave the site will be identified only by a participant identification number (Study ID) to maintain confidentiality. All paper records will be kept in a locked file cabinet. All computer entry and networking programs will be done using Study IDs only. Information will not be released without written permission of the participant, except as necessary for monitoring by IRB, the FDA, the NIA, and the OHRP.

11.4 Study Discontinuation

The study may be discontinued at any time by the IRB, the NIA, the OHRP, the FDA, or other government agencies as part of their duties to ensure that research participants are protected.

12 ETHICAL CONSIDERATIONS

The guiding ethical principles being followed by this study are in accordance with international policy, e.g. the Declaration of Helsinki, regarding ethical principles for medical research involving human subjects, and include the following considerations:

- that the study is designed to act in the best interests of our participants' health and well-being, and in fact participation in the study, which involves training in a mind-body intervention, is likely to improve their well-being;
- that it is designed to safeguard their health, including not over-burdening them with questionnaires and making sure that the intervention – which is a telephone based mindfulness training intervention, is reasonable in terms of amount of time being spent, and is evaluated in terms of safety, effectiveness, accessibility and quality;
- that it promotes equity and protection of the subjects' health and rights; that it recognizes that individual research subjects' rights and interest take precedence over the generation of new knowledge; that it protects the dignity, health, privacy and confidentiality of personal information of the research subjects by carefully following IRB procedures;
- that it causes minimum harm to the environment by minimizing amount of paper used where possible;
- that the research team members are all qualified and well trained health professionals competent to perform this research, and that they have taken the Good Clinical Practice training;
- that participants are appropriately compensated monetarily, but without being coerced into being in the study, and that they are expected to benefit from their participation in this research, with little or no harm expected to be caused by their participation in this research;
- that the confidentiality of data is carefully protected, and the consent forms appropriately describe any risks that could be caused, due to any breach of confidentiality, as well as possible benefits;
- that the research is being carried out on a non-vulnerable population, who are capable of giving informed consist;
- that the research was assessed via peer review and found to follow generally accepted scientific principles, and be based on a thorough knowledge of the scientific literature;
- that the design and proposed performance of the study is clearly described and justified in a research protocol, which has been submitted for review;
- that the protocol contains a statement (as described here) of the ethical considerations involved and addressed in this study;
- that the study is being submitted for consideration, guidance and approval to the UNC Committee on the Protection of Human Subjects, and that the principal investigators and the research team will provide monitoring information to the committee, especially any information about serious adverse events;
- and that the researchers plan to submit a final report of their study's findings and conclusions.

13 COMMITTEES

The study includes a Safety Monitoring Committee and an Advisory Council. The Safety Monitoring Committee will review adverse event data over the course of the study. The

Advisory Council will review study procedures and the intervention manual and make recommendations for study improvements.

14 PUBLICATION OF RESEARCH FINDINGS

Publication of the results of this trial will be governed by the policies and procedures of the University of North Carolina. Any presentation, abstract, or manuscript will be made available for review by NIA prior to submission.

15 REFERENCES

1. Alzheimer's Association. 2017 Alzheimer's Disease Facts and Figures. *Alzheimer's Dement*. 2017;13:325-373. https://www.alz.org/.
2. Weden MM, Shih RA, Kabeto MU, Langa KM. Secular Trends in Dementia and Cognitive Impairment of U.S. Rural and Urban Older Adults. *Am J Prev Med*. 2017;54(2):164-172. doi:10.1016/j.amepre.2017.10.021
3. Russ TC, Batty GD, Hearnshaw GF, Fenton C, Starr JM. Geographical variation in dementia: Systematic review with meta-analysis. *Int J Epidemiol*. 2012. doi:10.1093/ije/dys103
4. Steenland K, Goldstein FC, Levey A, Wharton W. A Meta-Analysis of Alzheimer's Disease Incidence and Prevalence Comparing African-Americans and Caucasians. *J Alzheimer's Dis*. 2015;50(1):71-76. doi:10.3233/JAD-150778
5. North Carolina Institute of Medicine. *Dementia - Capable North Carolina: A Strategic Plan for Addressing Alzheimer ' s Disease and Related Dementias*. Morrisville, NC; 2016. http://nciom.org/dementia-capable-north-carolina-a-strategic-plan-for-addressing-alzheimers-disease-and-related-dementias/.
6. Weden MM, Shih RA, Kabeto MU, Langa KM. Secular Trends in Dementia and Cognitive Impairment of U.S. Rural and Urban Older Adults. *Am J Prev Med*. 2017;54(2):164-172. doi:10.1016/j.amepre.2017.10.021
7. Black BS, Johnston D, Rabins P V., Morrison A, Lyketsos C, Samus QM. Unmet needs of community-residing persons with dementia and their informal caregivers: Findings from the maximizing independence at home study. *J Am Geriatr Soc*. 2013;61(12):2087-2095. doi:10.1111/jgs.12549
8. Pinquart M, Sörensen S. Differences between caregivers and noncaregivers in psychological health and physical health: A meta-analysis. *Psychol Aging*. 2003;18(2):250-267. doi:10.1037/0882-7974.18.2.250
9. Ory MG, Hoffman Iii RR, Yee JL, Tennstedt S, Schulz R. Prevalence and Impact of Caregiving: A Detailed Comparison Between Dementia and Nondementia Caregivers. 39(2):177-185.
10. Semple SJ. Conflict in alzheimer's caregiving families: Its dimensions and consequences. *Gerontologist*. 1992. doi:10.1093/geront/32.5.648
11. Peisah C, Brodaty H, Quadrio C. Family conflict in dementia: Prodigal sons and black sheep. *Int J Geriatr Psychiatry*. 2006. doi:10.1002/gps.1501
12. Tremont G, Davis JD, Bishop DS. Unique contribution of family functioning in caregivers of patients with mild to moderate dementia. *Dement Geriatr Cogn Disord*. 2006. doi:10.1159/000090699
13. Pinquart M, Sörensen S. Ethnic Differences in Stressors, Resources, and Psychological Outcomes of Family Caregiving: A Meta-Analysis. *Gerontologist*. 2005;45(1):90-106. doi:10.1093/geront/45.1.90
14. PJ D, Holt AM C. Factors Associated with Unmet Needs among African-American Dementia Care Providers. *J Gerontol Geriatr Res*. 2016;05(01):1-4. doi:10.4172/2167-

7182.1000267
15. Dilworth-Anderson P, Williams IC, Gibson BE. Issues of race, ethnicity, and culture in caregiving research: A 20-year review (1980-2000). *Gerontologist*. 2002;42(2):237-272. doi:10.1093/geront/42.2.237
16. Dilworth-Anderson P, Pierre G, Hilliard T. Social justice, health disparities, and culture in the care of the elderly. *J Law Med Ethics*. 2012;40(1):26-32. doi:10.1111/j.1748-720X.2012.00642.x
17. Merritt MM, McCallum TJ, Fritsch T. How much striving is too much? John Henryism active coping predicts worse daily cortisol responses for African-American but not White female dementia family caregivers. *Am J Geriatr Psychiatry*. 2011;19(5):451-460. doi:10.1097/JGP.0b013e3181eaffa4
18. Graham-Phillips A, Roth DL, Huang J, Dilworth-Anderson P, Gitlin LN. Racial and Ethnic Differences in the Delivery of the Resources for Enhancing Alzheimer's Caregiver Health II Intervention. *J Am Geriatr Soc*. 2016;64(8):1662-1667. doi:10.1111/jgs.14204
19. Badana ANS, Marino V, Haley WE. Racial Differences in Caregiving: Variation by Relationship Type and Dementia Care Status. *J Aging Health*. 2017:089826431774361. doi:10.1177/0898264317743611
20. McCallum TJ, Sorocco KH, Fritsch T. Mental Health and Diurnal Salivary Cortisol Patterns Among African American and European American Female Dementia Family Caregivers. *Am J Geriatr Psychiatry*. 2006;14(8):684-693. doi:10.1097/01.JGP.0000225109.85406.89
21. Whitfield KE, Allaire JC, Belue R, Edwards CL. Are Comparisons the Answer to Understanding Behavioral Aspects of Aging in Racial and Ethnic Groups? *Journals Gerontol Ser B Psychol Sci Soc Sci*. 2008;63(5):P301-P308. doi:10.1093/geronb/63.5.P301
22. Pearlin LI, Mullan JT, Semple SJ, Skaff MM. Caregiving and the stress process: an overview of concepts and their measures. *Gerontologist*. 1990;30(5):583-594. doi:10.1093/geront/30.5.583
23. Strawbridge WJ, Wallhagen MI. Impact of Family Conflict on Adult Child Caregivers 1.
24. Shelton EG, Orsulic-Jeras S, Whitlatch CJ, Szabo SM. Does it Matter if We Disagree? The Impact of Incongruent Care Preferences on Persons with Dementia and Their Care Partners. *Gerontologist*. 2017;00(00):gnw202. doi:10.1093/geront/gnw202
25. Strawbridge WJ, Wallhagen MI. Impact of family conflict on adult child caregivers. *Gerontologist*. 1991;31(6):770-777. doi:10.1093/geront/31.6.770
26. Mitrani VB, Lewis JE, Feaster DJ, Czaja SJ. The Role of Family Functioning in the Stress Process of Dementia Caregivers : ... *Gerontologist*. 2006;46(1):97-105.
27. Mishel MH. Reconceptualization of the Uncertainty in Illness Theory. *Image J Nurs Sch*. 1990;22(4):256-262.
28. Mishel MH. Theories of Uncertainty in Illness. In: Smith MJ, Liehr PR, eds. *Middle Range Theory for Nursing*. Third. New York: Springer Publishing Company, LLC; 2014:74-107.
29. Unson C, Flynn D, Glendon MA, Haymes E, Sancho D. Dementia and Caregiver Stress: An Application of the Reconceptualized Uncertainty in Illness Theory. *Issues Ment Health Nurs*. 2015;36(6):439-446. doi:10.3109/01612840.2014.993052
30. Moore A, Malinowski P. Meditation, mindfulness and cognitive flexibility. *Conscious Cogn*. 2009. doi:10.1016/j.concog.2008.12.008
31. Garland EL. The meaning of mindfulness: A second-order cybernetics of stress, metacognition, and coping. *Complement Health Pract Rev*. 2007;12(1):15-30. doi:10.1177/1533210107301740
32. Garland E, Gaylord S. Envisioning a Future Contemplative Science of Mindfulness: Fruitful Methods and New Content for the Next Wave of Research. *Complement Health*

Pract Rev. 2009;14(1):3-9. doi:10.1177/1533210109333718.Envisioning
33. Lutz A, Slagter HA, Dunne JD, Davidson RJ. Attention regulation and monitoring in meditation. *Trends Cogn Sci*. 2008;12(4):163-169. doi:10.1016/j.tics.2008.01.005
34. Greeson JM. Mindfulness Research Update: 2008. *Complement Health Pract Rev*. 2009;14(1):10-18.
35. Khoury B, Lecomte T, Fortin G, et al. Mindfulness-based therapy: A comprehensive meta-analysis. *Clin Psychol Rev*. 2013;33(6):763-771. doi:10.1016/j.cpr.2013.05.005
36. Woods-Giscombé CL, Gaylord SA. The Cultural Relevance of Mindfulness Meditation as a Health Intervention for African Americans: Implications for Reducing Stress-Related Health Disparities. *J Holist Nurs*. 2014;32(3):147-160. doi:10.1177/0898010113519010
37. Liu Z, Chen QL, Sun Y. Mindfulness training for psychological stress in family caregivers of persons with dementia: a systematic review and meta-analysis of randomized controlled trials. *Clin Interv Aging*. 2017;Volume 12:1521-1529. doi:10.2147/CIA.S146213
38. Li G, Yuan H, Zhang W. The Effects of Mindfulness-Based Stress Reduction for Family Caregivers: Systematic Review. *Arch Psychiatr Nurs*. 2016;30(2):292-299. doi:10.1016/j.apnu.2015.08.014
39. Cheryl L. Woods-Giscombe, Gaylord SA, Li Y, et al. Mindfulness-Based Diabetes Education for African Americans with Prediabetes: A Pilot, Sequential Mixed-Methods, Two-Arm, Randomized Clinical Trial. *Diabetes Educ*.
40. Whitebird RR, Kreitzer M, Crain AL, Lewis BA, Hanson LR, Enstad CJ. Mindfulness-Based Stress Reduction for Family Caregivers: A Randomized Controlled Trial. *Gerontologist*. 2013;53(4):676-686. doi:10.1093/geront/gns126
41. Schellekens MPJ, Karremans JC, van der Drift MA, et al. Are Mindfulness and Self-Compassion Related to Psychological Distress and Communication in Couples Facing Lung Cancer? A Dyadic Approach. *Mindfulness (N Y)*. 2017;8(2):325-336. doi:10.1007/s12671-016-0602-0
42. Amutio-Kareaga A, García-Campayo J, Delgado L, Hermosilla D, Martínez-Taboada C. Improving Communication between Physicians and Their Patients through Mindfulness and Compassion-Based Strategies: A Narrative Review. *J Clin Med*. 2017;6(3):33. doi:10.3390/jcm6030033
43. Spijkerman MPJ, Pots WTM, Bohlmeijer ET. Effectiveness of online mindfulness-based interventions in improving mental health: A review and meta-analysis of randomised controlled trials. *Clin Psychol Rev*. 2016;45:102-114. doi:10.1016/j.cpr.2016.03.009
44. Jayewardene WP, Lohrmann DK, Erbe RG, Torabi MR. Effects of preventive online mindfulness interventions on stress and mindfulness: A meta-analysis of randomized controlled trials. *Prev Med Reports*. 2017;5:150-159. doi:10.1016/j.pmedr.2016.11.013
45. Rosen RK, McGarrity LA, Salmoirago-Blotcher E, Rich C, Rana A, Carey MP. Telephone-Delivered Mindfulness Training for People Living with HIV: A Qualitative 360° Inquiry. *AIDS Behav*. 2017;21(11):3194-3201. doi:10.1007/s10461-017-1857-8
46. Gross CR, Reilly-Spong M, Park T, Zhao R, Gurvich O V., Ibrahim HN. Telephone-adapted Mindfulness-based Stress Reduction (tMBSR) for patients awaiting kidney transplantation. *Contemp Clin Trials*. 2017;57(March):37-43. doi:10.1016/j.cct.2017.03.014
47. Aivaliotis VI, Lee Y, Zia J, Wassef W, Abramson M, Park W. Telephone-Based Mindfulness Therapy Intervention for Patients with Chronic Pancreatitis. *Dig Dis Sci*. 2017;62(2):502-509. doi:10.1007/s10620-016-4389-6
48. Cox CE, Porter LS, Buck PJ, et al. Development and preliminary evaluation of a telephone-based mindfulness training intervention for survivors of critical illness. *Ann Am Thorac Soc*. 2014;11(2):173-181. doi:10.1513/AnnalsATS.201308-283OC
49. Bédard M, Molloy DW, Squire L, Dubois S, Lever JA, O'donnell M. The Zarit Burden Interview: A new short version and screening version. *Gerontologist*. 2001;41(5):652-657.

doi:10.1093/geront/41.5.652
50. Garnefski N, Kraaij V. Cognitive emotion regulation questionnaire - development of a short 18-item version (CERQ-short). *Pers Individ Dif*. 2006;41(6):1045-1053. doi:10.1016/j.paid.2006.04.010
51. Carleton RN, Norton MAPJ, Asmundson GJG. Fearing the unknown: A short version of the Intolerance of Uncertainty Scale. *J Anxiety Disord*. 2007;21(1):105-117. doi:10.1016/j.janxdis.2006.03.014
52. Hale W, Richmond M, Bennett J, et al. Resolving uncertainty about the intolerance of uncertainty scale-12: Application of modern psychometric strategies. *J Pers Assess*. 2016;98(2):200-208. doi:10.1080/00223891.2015.1070355
53. Gruber-Baldini AL, Velozo C, Romero S, Shulman LM. Validation of the PROMIS® measures of self-efficacy for managing chronic conditions. *Qual Life Res*. 2017;26(7):1915-1924. doi:10.1007/s11136-017-1527-3
54. Broderick J, DeWit EM, Rothrock N, Crane P, Forrest CB. Advances in Patient Reported Outcomes: The NIH PROMIS Measures. *eGEMs (Generating Evid Methods to Improv patient outcomes)*. 2013;1(1):12. doi:10.13063/2327-9214.1015
55. Schalet BD, Pilkonis PA, Yu L, et al. Clinical validity of PROMIS Depression, Anxiety, and Anger across diverse clinical samples. *J Clin Epidemiol*. 2016;73:119-127. doi:10.1016/j.jclinepi.2015.08.036
56. Hays RD, Spritzer KL, Thompson WW, Cella D. U.S. General Population Estimate for "Excellent" to "Poor" Self-Rated Health Item. *J Gen Intern Med*. 2015;30(10):1511-1516. doi:10.1007/s11606-015-3290-x
57. Raes , F ., Pommier , E ., Neff , K . D ., & Van Gucht D. Construction and factorial validation of a short form of the Self-Compassion Scale. 2011;255(May 2016):10-11. doi:10.1002/cpp.702
58. Neff KD, Whittaker TA, Karl A. Examining the Factor Structure of the Self-Compassion Scale in Four Distinct Populations: Is the Use of a Total Scale Score Justified? *J Pers Assess*. 2017;99(6):596-607. doi:10.1080/00223891.2016.1269334
59. Olson DH. Family Satisfaction Scale (FSS). http://www.laviecounseling.org/vfh/vfhasm/FACESIV.FamilySatisfactionScale.pdf. Accessed February 2, 2018.
60. Underhill AT, LoBello SG, Fine PR. Reliability and validity of the Family Satisfaction Scale with survivors of traumatic brain injury. *J Rehabil Res Dev*. 2004;41(4):603. doi:10.1682/JRRD.2003.06.0094
61. Kaufer DI, Cummings JL, Ketchel P, et al. Validation of the NPI-Q, a Brief Clinical Form of the Neuropsychiatric Inventory. *J Neuropsychiatry Clin Neurosci*. 2000;12(2):233-239. doi:10.1176/jnp.12.2.233
62. Cummings JL, Mega M, Gray K, Rosenberg-Thompson S, Carusi DA, Gornbein J. The neuropsychiatric inventory. *Neurology*. 1994;44(December):2308-2314.
63. Reisberg B. Functional assessment staging (FAST). *Psychopharmacol Bull*. 1988;24(4):653-659. http://www.ncbi.nlm.nih.gov/pubmed/3249767. Accessed February 11, 2018.
64. Sclan SG, Ph D, Reisberg B. Functional Assessment Staging (FAST) in Alzheimer ' s Disease : Reliability , Validity , and Ordinality. 1992;4.
65. Auer S, Reisberg B. The GDS/FAST Staging System. *Int Psychogeriatrics*. 1997;9(S1):167-171. doi:10.1017/S1041610297004869

Provide the citations for all publications and presentations referenced in the text of the protocol.

15.1.1 Appendix A.1: **Periodic Telephone Administered Adverse Event Monitoring Form**

STUDY ID:_____

Date:_____

1**. In the past week**, have you:

a. been hospitalized for any reason?	☐No	☐Yes (Please explain):
b. experienced any life-threatening events?	☐No	☐Yes (Please explain):
c. given birth to a child with birth defects?	☐No	☐Yes (Please explain):
d. become physically disabled in some way?	☐No	☐Yes (Please explain):
e. experienced any new or worsening emotional health problems (for example, worry, nervousness, sadness, or stress)?	☐No	☐Yes *(Please explain, including if participant feels change is related to study participation):* Also, if yes, administer the PROMIS Anxiety SF. *If the participant's T scores increase by >9 points and the T score is >65, consult with the PIs.*
e. experienced any new or worsening physical health problems <u>that you think might be related to being part of this study</u>?	☐No	☐Yes (Please explain):

_____ _____ _____

Signature of study personnel completing form *Print Name* *Date*

15.1.2 Appendix A.2: **Adverse Event (AE) Reporting Form (version 1.0)**

Adverse Event (AE) Reporting Form

Protocol Title: Click or tap here to enter text.

Protocol Number: Click or tap here to enter text.

Study ID: Click or tap here to enter text.

---

1. AE Onset Date: Click or tap to enter a date.
2. AE Stop Date: Click or tap to enter a date.
3. Location of adverse event: Click or tap here to enter text.
4. Was this an unexpected adverse event?

   ☐ YES ☐ NO

5. Brief description of participant with no personal identifiers:

Sex: ☐ Female ☐ Male Age: Click or tap here to enter text.

6. Adverse Event Term(s):

Click or tap here to enter text.

7. Brief description of the nature of the adverse event (attach description if more space needed):

Click or tap here to enter text.

8. Category of the adverse event:

   ☐ Death (date): Click or tap to enter a date. ☐Other: Click or tap here to enter text.

   ☐ Life threatening

   ☐ Hospitalization – initial or prolonged

   ☐ Disability / incapacity

9. Relationship of event to intervention:

☐ Unrelated (clearly not related to the intervention)

☐ Possible (may be related to the intervention)

☐ Definite (clearly related to intervention)

10. Was study intervention discontinued due to event?

☐ YES ☐NO

11. What medication or other steps were taken to treat adverse event?

Click or tap here to enter text.

12. List any relevant tests, laboratory data, history, including preexisting medical conditions.

Click or tap here to enter text.

13. Type of report:

☐ Initial

☐ Follow-up

☐ Final

Signature of Principal Investigator: Click or tap here to enter text.

Date: Click or tap to enter

15.2 Consent Forms

IRB TEMPLATE
Version 2.0-12/5/2018

****DO NOT CHANGE THIS FIELD-IRB USE ONLY****

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants
Consent Form Version Date: January 3, 2021
IRB Study # 19-0053
Title of Study: Easing the Burden of Dementia Caregiving: A Telephone-delivered Mindfulness Intervention for Rural, African American Families
Short Name of Study: Mindful Coping and Communication in Caregiving (MC3)
Principal Investigator: Susan Gaylord
Principal Investigator Department: Physical Medicine and Rehabilitation
Principal Investigator Phone number: (919) 966-8586
Principal Investigator Email Address: gaylords@med.unc.edu
Funding Source and/or Sponsor: National Institutes of Health (NIH)

Study Contact Telephone Number: (919) 370-6744
Study Contact Email: mc3@med.unc.edu

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary. You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to understand if mindfulness-based stress reduction (MBSR) training is helpful training for lowering the burden for caregivers of persons with Alzheimer's disease and related dementia (ADRD). The MBSR training will happen over the phone, which is known as telephone-based mindfulness training intervention (TMT). Our training will be for rural African American or Black caregivers. We are testing to see if it is appropriate to do MBSR training over the phone with African American caregivers.
This project will test the following:

- determine how and why a TMT may be helpful in lowering caregiver burden among rural, African American caregiving teams of persons with ADRD;
- look at how TMT may impact emotional and physical health, uncertainty, family conflict and support between caregivers, and confidence of the caregiver;
- learn if technology over the phone, internet, and tablet will help rural African American caregivers get access to educational resources.

We will ask questions to caregivers through interviews to answer what the project is testing.

You are being asked to be in the study because you are an African American or Black caregiver of a person with ADRD who lives in a rural area.

Are there any reasons you should not be in this study?
You should not be in this study if you:

- do not identify as African American or Black
- do not live in a rural area
- do not have a telephone to use for the telephone training
- are being treated for cancer
- have been hospitalized 3 times in the past year
- do not care for a person with a dementia or Alzheimer's diagnosis
- do not provide care for a person with ADRD for 4 or more hours in a day
- do not have someone who shares caregiving or helps make decisions regarding the person with ADRD

How many people will take part in this study?
There will be approximately 64 people in this research study.

What will happen if you take part in the study?
If you join the project, we will go through the following steps with you:

- ***Enrollment Visit***: This visit will be in-person at your home or over the phone. At this visit we will give you more about the project, get your consent to join, and do surveys with you. We can speak with your care partner either in-person or over the phone. During this visit we will complete:
    - ***Consent***: We will review the consent form with you. You will have the chance to ask us any questions about the study before signing the consent.
    - ***Pre-participation Interview:*** We will ask you questions to get your thoughts about mindfulness, how helpful you think telephone mindfulness training will be, and how comfortable you are using technology.

    - ***Baseline Assessments***: You will be asked to answer questionnaires about different stresses related to caregiving, how you deal with difficult emotions, your social support, how you communicate with your family, how you use mindfulness, and symptoms experienced by the person you care for. The study staff will ask you each question, but you can complete it on paper or online, if you prefer.

- ***Telephone-based Mindfulness Training (TMT)***:

- ***Weekly Sessions:*** You and your care partner will be asked to call in to the telephone training for one hour per week for 8 weeks with three other families. A mindfulness instructor will introduce you to mindfulness and lead you through different practices.

  We will check in with you at 3 different time points while you're participating in the weekly sessions to see if your caregiving distress is changing.

- ***Home Assignments*****:** Home assignments are a key element of TMT weekly sessions. You will be assigned daily home practice based on the previous weeks' content. Most weeks will also include one assignment to be carried out with your care-partner, either over the phone or in-person. Home assignments range from 10-minute practices, to reflections, to interactive discussions among care-partners. For example, you might be asked to eat mindfully or listen mindfully while you're around the person you're caring for. Mindful practices will be given to you either on a CD, paper handouts, or through downloadable recordings onto your computer or Smartphone.

- ***Saturday Retreat:*** One Saturday during the 8 weeks you will be invited to attend a retreat where you can meet the other families. The study will help cover the cost of hiring someone to stay with your relative during that time, if you need it. The retreat will occur in-person. In the event of adverse weather or situations, the retreat will take place over the phone or using video conference. The retreat will be up to 4 hours, depending on whether in person, over the telephone, or via video conference.

In addition to the telephone classes and retreat, we will give you and your care partner a notebook with information on local and national resources for people with memory disorders and the families who care for them. We will also put the information on a tablet for some of the participants.

- ***Follow-up Visit***: Within 4 weeks of the last telephone session being completed, we will complete a follow-up visit with you. This visit will occur in-person at your home or over the phone. We will go through the questionnaires and get your opinion about the telephone training. Your feedback will help us make the program better so that it can be more helpful to caregiving families.

  - ***Post-participation Interview:*** We will ask you questions to get your thoughts about the telephone sessions in which you participated.

  - ***Follow-up Assessments:*** You will be asked questionnaires like those completed for the baseline assessment. We will not ask you about symptoms experienced by the person you care for. The study staff will ask you each question, but you can complete it on paper or online, if you prefer.

How long will your part in this study last?
You will be in the study for up to 12 weeks. It will take the following amount of time to complete activities for the study:

- Enrollment Visit (Total = 1 hour 45 minutes). The total time includes:
  - Consent = 30 minutes
  - Pre-participation Interview = 10-15 minutes
  - Baseline Assessments = 1 hour
- TMT training (Total= up to 12 hours 15 minutes). The total time includes:
  - 8 weekly sessions = 1 hour each session (8 hours)
  - Saturday group retreat = up to 4 hours
  - 3 check-in calls = 5 minutes each (15 minutes)
- Follow-up Visit (Total = 1 hour 45 minutes). The total time includes:
  - Post-participation Interview = 30-45 minutes
  - Follow-up Assessments = 1 hour

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. Our study hopes you will benefit from the telephone training and resources we provide, but we cannot guarantee that you will.

What are the possible risks or discomforts involved from being in this study?
During the study, you may feel uncomfortable about some of the questions we ask you. You may also feel embarrassed, agitated or anxious during the telephone training (TMT), especially if you become more aware of negative thoughts, emotions, or how your body feels.
There may be uncommon or previously unknown risks. You should report any problems to the researcher.

Will I receive any other clinical results?
You will not receive any clinical results during this study.

How will information about you be protected?
We will use a secure web system to protect your privacy and confidentiality. Only research team members with login rights can see your information. We will use ID numbers to identify you. The file that links your name and ID number will be maintained in our secure web system that can only be accessed by a few members of the research team.

Participants will not be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent. We also may contact you about future research opportunities.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.
Also, the telephone sessions (TMT) will be audio recorded.

- Audio recordings will be collected during telephone sessions by the instructor.
- The instructor will give audio recordings to the team member who will type out a document of everything on the audio recording from each session. The team member typing the document will identify each person talking on the audio recording as an ID number, instead of your name. After the document is reviewed by the research team, the audio recording will be destroyed.
- You can request that audio recordings be turned off during times when you would like to share something that you do not want to be reviewed by the research team.

Check the line that best matches your choice:

____ OK to record me during the study
_____ Not OK to record me during the study

Participants must agree not to reveal anything they learn from about others during the telephone group sessions.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction to the training, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?
You can receive up to $100 for completing study visits. Payment will be provided for:

- ***Enrollment Visit:***
  - Pre-participation Interview: $25
  - Baseline Assessments: $25
- ***Follow-up Visit:***
  - Post-participation Interview: $25
  - Follow-up Assessments: $25

We will also give you up to $99 to cover costs of care for your relative during the Saturday Retreat. This will be given to you only if you need it.

All payments will be given to you on a Visa reloadable gift card. You will keep the same gift card for the entire study.

Any payment provided for participation in this study may be subject to applicable tax withholding obligations.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

Who is sponsoring this study?
This research is funded by National Institute on Aging. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What is a Certificate of Confidentiality?
Most people outside the research team will not see your name on your research information. This includes people who try to get your information using a court order in the United States. One exception is if you agree that we can give out research information with your name on it or for research projects that have been approved under applicable rules. Other exceptions are for information that is required to be reported under law, such as information about child or disabled abuse or neglect or certain harmful diseases that can be spread from one person to another. Personnel of a government agency sponsoring the study may also be provided information about your involvement in the research study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:
I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____
Signature of Research Participant Date

_____
Printed Name of Research Participant

_____ _____
Signature of Research Team Member Obtaining Consent Date

_____
Printed Name of Research Team Member Obtaining Consent

University of North Carolina-Chapel Hill
Consent Addendum for Unencrypted Communication

Consent Form Version Date: December 11, 2020
IRB Study # 19-0053
Title of Study: Easing the Burden of Dementia Caregiving: A Telephone-delivered Mindfulness Intervention for Rural, African American Families
Short Name of Study: Mindful Coping and Communication in Caregiving (MC3)
Principal Investigator: Dr. Susan Gaylord
Principal Investigator Department: Physical Medicine and Rehabilitation
Principal Investigator Phone number: (919) 966-8586
Principal Investigator Email Address: gaylords@med.unc.edu
Funding Source and/or Sponsor: National Institutes of Health (NIH)
Study Contact Telephone Number: (919) 370-6744
Study Contact Email: mc3@med.unc.edu

The following information is regarding un-encrypted communication (e.g., texting or email) by study staff and should be read as an addition to the consent information you have already been provided. All information previously provided is still true and remains in effect. Your participation continues to be voluntary. You may refuse to participate or may withdraw your consent to participate at any time, and for any reason, without jeopardizing your future care at this institution or your relationship with your study team.

The study team would like to message you by texting and/or e-mail. However, you may say "no" to receiving these messages and still participate in this study. If you say "yes", messages may contain personal information about you and may be sent or received by the study team's personal electronic devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team. This information may include information such as reminders and notifications to contact the study team.

If you wish to stop receiving unprotected communication from the study team or have lost access to your device, please notify the study team using the study contact information on the first page of this addendum to the consent. After the study is complete and all research activities finished, or you withdraw from the study or request to stop receiving unprotected communication, you will no longer receive un-encrypted (un-protected) messages specific to this study.

_____ Yes, I consent to the study team utilizing the following cell phone/email address to send communication: _____

_____ No, I do not consent to receive un-protected communication from the study team.

Subject's Agreement: I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to continue to participate in this research study.