

**AWARD NUMBER:** W81XWH-17-1-0326

**TITLE:** Practice of Acceptance, Awareness, and Compassion in Caregiving (PAACC)

**PRINCIPAL INVESTIGATOR:** Mamta Sapra, MD

**CONTRACTING ORGANIZATION:** Salem Research Institute, Salem, VA

**REPORT DATE:** October 2022

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<b>14. ABSTRACT</b> Caregiving for individuals with Alzheimer's disease and related dementias (ADRD) and Traumatic Brain Injury-related dementia has been associated with increased risk of both psychiatric morbidity and mortality, including higher risks of depression, anxiety, poor quality of life, and even early mortality. Although there are several beneficial interventions for caregivers of persons with AD, interventions that can help build skills to recognize and manage stress as well as enhance compassion in caregivers are urgently needed. The purpose of this study is to evaluate the effectiveness of proposed intervention, Practice of Acceptance, Awareness, and Compassion in Caregiving (PAACC) that integrates mindfulness training with caregiving skills training. Several studies have shown effectiveness of mindfulness in decreasing caregiver burden in caregivers of individuals with cognitive deficits, but most of them did not provide caregiving skills training with mindfulness. Our study hypothesis is that intervention such as PAACC which combines education, skill building, and mindfulness practices will enhance caregiving skills and will reduce caregiver stress as well as increase quality of life of the care recipient. The objective of the study will be accomplished by conducting a randomized control trial to test effectiveness of PAACC and compare it with existing cognitive behavior-based intervention called Resources for Enhancing Alzheimer's Caregiver Health (REACH).		

<b>15. SUBJECT TERMS</b> Dementia, caregivers, mindfulness, compassion, clinical trial, intervention					
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## 2. INTRODUCTION:

Caregiving for individuals with Alzheimer’s disease and related dementias (ADRD) and Traumatic Brain Injury-related dementia has been associated with increased risk of both psychiatric morbidity and mortality, including higher risks of depression, anxiety, poor quality of life, and even early mortality. Although there are several beneficial interventions for caregivers of persons with AD, interventions that can help build skills to recognize and manage stress as well as enhance compassion in caregivers are urgently needed. The purpose of this study is to evaluate the effectiveness of proposed intervention, Practice of Acceptance, Awareness, and Compassion in Caregiving (PAACC) that integrates mindfulness training with caregiving skills training. Several studies have shown effectiveness of mindfulness in decreasing caregiver burden in caregivers of individuals with cognitive deficits, but most of them did not provide caregiving skills training with mindfulness. Our study hypothesis is that intervention such as PAACC which combines education, skill building, and mindfulness practices will enhance caregiving skills and will reduce caregiver stress as well as increase quality of life of the care recipient. The objective of the study will be accomplished by conducting a randomized control trial to test effectiveness of PAACC and compare it with existing cognitive behavior-based intervention called Resources for Enhancing Alzheimer’s Caregiver Health (REACH).

## 3. KEYWORDS:

Dementia, caregivers, mindfulness, compassion, clinical trial, intervention

## 4. ACCOMPLISHMENTS

### What were the major goals of the project?

The primary aims of the project are:

Aim 1: To evaluate the effectiveness of mindfulness-based caregiver intervention (PAACC) that also includes dementia care skill- building components.

Aim 2: To evaluate the effectiveness of PAACC compared to an established dementia caregiver intervention (REACH-VA) in improving caregiver burden and quality of life of the care recipient.

The first major task listed for these goals in SOW for year 1 are hire and train study personnel, obtain regulatory approvals. The second major task is to start and continue recruitment and implementation of both interventions. The Major task for year 2 and 3 is ongoing continued recruitment for the trial. The major task for year 5(NCE) has been ongoing recruitment and enrollment to reach target numbers.

## What was accomplished under these goals?

Below we describe our project milestones for Year 1, Year 2, Year 3, Year 4 and Year 5

Human Subject Proposals to IRB for Salem and Boston VA sites	Completed	The project has been approved by Veteran Affairs Central Institution Review Board for Salem and Boston VA sites. Regulatory approval has been completed and received from DoD Human Research Protection Office. Local Research and Development Committee approval obtained at both sites. Annual continuing review approvals obtained for both sites as well from Central Institutional Review Board.
Developed guidelines with defined roles for all members of the study team	Completed	Guidelines have been created. Weekly telephone meetings with the team are being conducted.
Assessment instruments	Completed	All assessment instruments have been gathered and have been programmed in Redcap.
Intervention Manuals with written instructions for administering the treatment protocol	Completed	Intervention manuals and Caregiver notebook has been created and 100 copies have been made. Audio-CDs for the mindfulness scripts have also been created and 100 copies have been created.
Hire Research Assistants at Salem and Boston VA sites	Completed	Research Assistants have been hired and trained at both Salem and Boston site.
Recruitment and enrollment at Boston, VA	Complete	Boston site enrolled 21 participants, randomized 17 and completed 14. Boston site has been closed to move of the investigator.
Recruitment at Salem, VA	Ongoing	Salem is actively recruiting participants. Currently we have 91 completed the study, 5 active at present in the study at Salem. We will continue to recruit actively to meet our target which is 8 more to be enrolled.

In year 3, Boston site was closed due to move of the local site investigator. For the year 3, research activities were on hold due to ongoing COVID-19 pandemic. The protocol was changed in Year4 for an option of completing study visits virtually through telehealth without changing any structure of the visits including the intervention and regulatory approvals were obtained for this change through Institutional Review Board as well as Human Research Protection Office. Recruitment has been ongoing with average rate of 3-4 subjects per month. The study team hopes to reach its target in next few months.

Here is **interim data summary** with primarily baseline descriptive data: 105 caregivers have completed the intervention (mean age of 67 y/o, 80% female, 14% African American). Seventy percent of the sample has been a spousal caregiver. Nearly 76% of the sample have greater than a high school education. 60% of caregivers rated their health as good. The most commonly used services were medical care services, transportation, rehab services, as well as caregiver support groups, and respite care. The least commonly used service was meal delivery, personal care and homemaker

**What opportunities for training and professional development has the project provided?**

Nothing to Report

**How were the results disseminated to communities of interest?**

Nothing to Report

**What do you plan to do during the next reporting period to accomplish the goals?**

We continue to recruit at rate of 4-5 subjects per month to reach our target numbers at VA medical center, Salem, Virginia and soon aim to reach our target over the next few months.

**4. IMPACT:**

**What was the impact on the development of the principal discipline(s) of the project?**

Nothing to Report

**What was the impact on other disciplines?**

Nothing to Report

**What was the impact on technology transfer?**

Nothing to Report

**What was the impact on society beyond science and technology?**

Nothing to Report

**5. CHANGES/PROBLEMS**

Nothing to Report

**Actual or anticipated problems or delays and actions or plans to resolve them**

No specific problems identified at this time.

**Changes that had a significant impact on expenditures**

We plan to use the remaining funds for continued recruitment and for personnel to finish up the study and reach our target for the study. Spend plan has been reviewed and approved.

**Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

**Significant changes in use or care of human subjects**

Nothing to Report

**Significant changes in use or care of vertebrate animals**

Nothing to Report

**Significant changes in use of biohazards and/or select agents**

Nothing to Report

**6. PRODUCTS:**

**Publications, conference papers, and presentations**

**Journal publications**

Nothing to Report

**Books or other non-periodical, one-time publications**

Nothing to Report

**Other publications, conference papers and presentations**

**The study team presented a poster at Annual meeting of Southern Gerontological Society in April 2022 on baseline descriptive data as well as on relationship between perceived stress and rumination.**

**Website(s) or other Internet site(s)**

Nothing to Report

**Technologies or techniques**

Nothing to Report

**Inventions, patent applications, and/or licenses**

Nothing to Report

- **Other Products**

Nothing to Report

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

### What individuals have worked on the project?

*Name:* Mamta Sapra

*Project Role:* PI

*Researcher Identifier (e.g. ORCID ID):*

*Nearest person month worked:* 2

*Contribution to Project:* Dr. Sapra is the study PI

*Funding Support:* Dr. Sapra's salary is supported by Veteran Affairs Medical Center. Dr. Sapra is full time VA employee

*Name:* Judy Grause

*Project Role:* Research Coordinator

*Researcher Identifier (e.g. ORCID ID):*

*Nearest person month worked:* 4

*Contribution to Project:* IRB and regulatory coordination, support in team communication, logistics, manage and help with recruitment, scheduling.

*Funding Support:*

### Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to Report

### 8. What other organizations were involved as partners?

Nothing to Report

**9. APPENDICES: See attached Quad chart**  
**See included Quad Chart**

**Practice of Acceptance, Awareness, and Compassion in Caregiving (PAACC)**

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PI: Mamta Sapra, MD

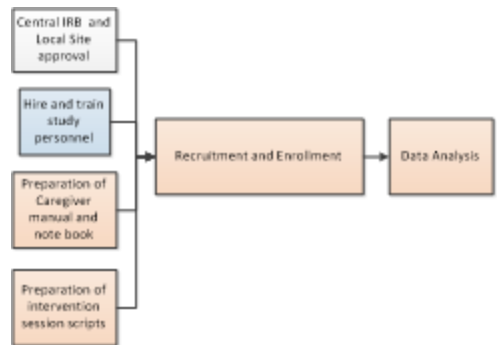
Org: Salem Research Institute, Inc.

\$485,406



**Study/Product Aim(s)**  
 Aim 1: Evaluate the effectiveness of a mindfulness-based caregiver intervention, Practice of Acceptance, Awareness, and Compassion in Caregiving (PAACC) that also includes dementia care skill-building.  
 Aim 2: Evaluate the effectiveness of PAACC compared to an established dementia caregiver intervention, Resources for Enhancing Alzheimer's Caregiver Health (REACH-VA) in improving caregiver burden and quality of life of care recipient.

**Approach**  
 Approach is to conduct an conducting a randomized controlled trial to test the effectiveness of PAACC and compare it with existing multi-component cognitive-behavior based intervention called Resources for Enhancing Alzheimer's Caregiver Health (REACH).



**Goals/Milestones**  
**Year 1 Goals Achieved** – Hire and train study personnel, obtain regulatory approval, Start recruitment  
 • Central Institutional Review Board and HRPO approvals accomplished. Study personnel hired and trained.  
 • Caregiver manual, script and intervention designed .  
 • Recruitment started and ongoing  
**Year 2 Goals** – Complete target recruitment for year 2 and preliminary data analysis  
 • Recruitment and enrollment ongoing.  
**Year 3 Goals** – Reach target recruitment and complete study data.  
**Year 4 and 5 Goal** s- Ongoing recruitment and continue to reach for target planned.  
**Comments/Challenges/Issues/Concerns:** Recruitment ongoing at a good pace.

Acti				
Regulatory Approvals				
Preparatory Tasks				
Subject Recruitment			Ongoing	Ongoing
Enter +Clean Study Data			Ongoing	Ongoing
Data Analysis				Preliminary
Write and submit results				