

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 2021

TYPE OF REPORT: Annual

**PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012**

DISTRIBUTION STATEMENT: Approved for Public Release; Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGEForm Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

1. REPORT DATE October 2021	2. REPORT TYPE Annual	3. DATES COVERED 15Sep2020-14Sep2021
---------------------------------------	---------------------------------	--

4. TITLE AND SUBTITLE: Practice of Acceptance, Awareness, and Compassion in Caregiving (PAACC)	5a. CONTRACT NUMBER W81XWH-17-1-0326
	5b. GRANT NUMBER
	5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S) Mamta Sapra, MD , mamta.sapra@va.gov E-Mail:mamta.sapra@va.gov	5d. PROJECT NUMBER
	5e. TASK NUMBER
	5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) SALEM RESEARCH INSTITUTE INC 1970 ROANOKE BLVD (151) SALEM VA 24153-6404	8. PERFORMING ORGANIZATION REPORT NUMBER
---	---

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Development Command Fort Detrick, Maryland 21702-5012	10. SPONSOR/MONITOR'S ACRONYM(S)
	11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT 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).
--

15. SUBJECT TERMS Dementia, caregivers, mindfulness, compassion, clinical trial, intervention					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT Unclassified	18. NUMBER OF PAGES 10	19a. NAME OF RESPONSIBLE PERSON USAMRDC
a. REPORT Unclassified	b. ABSTRACT Unclassified	c. THIS PAGE Unclassified			19b. TELEPHONE NUMBER <i>(include area code)</i>

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

TABLE OF CONTENTS

	<u>Page</u>
1. Introduction.....	5
2. Keywords	5
3. Accomplishments.....	5
4. Impact.....	7
5. Changes/Problems.....	7
6. Products.....	8
7. Participants & Other Collaborating Organizations.....	9
8. Special Reporting Requirements.....	10
9. Appendices.....	10

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 4(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 and Year 4

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 79 completed the study, 8 active right now in the study at Salem. We will continue to recruit actively to meet our target.

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. In year 4, recruitment has been ongoing and picked up in the last six months with average rate of 3-4 subjects per month. The study team hopes to continue at this rate to reach target number.

Here is **interim data summary** with primarily baseline descriptive data: 93 caregivers have completed the intervention (mean age of 66 y/o, 80% female, 14% African American). Seventy percent of the sample has been a spousal caregiver. Nearly 75% 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 services.

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 will continue to recruit at rate of 4-5 subjects per month to reach our target numbers at VA medical center, Salem, Virginia as the pandemic allows. The approved option of choice of completing visits virtually has helped the team with ongoing enrollment. We have been advertising for hiring another interventionist for the project who will help us to have higher number of participants doing intervention at any given time period. Hiring of an interventionist has been difficult due to ongoing COVID pandemic.

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 except difficulty hiring an interventionist to help with the project to move faster and enroll higher number of participants. We have reached out to surrounding counseling graduate schools this month and hope to get some response of interested applicants. In the meantime, we have continued to enroll at a rate of four subjects per month in the last few months. Also planning to advertise the position through different avenues and platforms.

Changes that had a significant impact on expenditures

Delay in completion of the study due to COVID pandemic and slower recruitment through the last 1 ½ year has had impact on expenditure. We do plan to use the remaining funds for continued recruitment, but also to hire another interventionist to speed up the process of enrollment.

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

A paper presentation on preliminary data will be presented at this year's Annual Gerontological Society of America meeting in Arizona.

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: Tonda Yates

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)

W81XWH-17-1-0326

PI: Mamta Sapra, MD

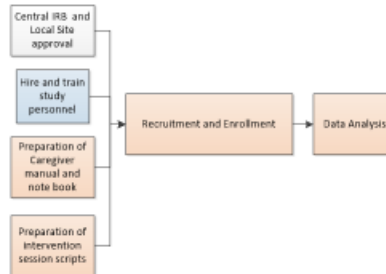
Org: Salem Research Institute, Inc.

Award Amount: \$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 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).



Activities	Year 1	Year 2	Year 3	Year 4(NCE)
Regulatory Approvals	✓	✓	✓	✓
Preparatory Tasks	✓	✓	✓	✓
Subject Recruitment	✓	✓	✓	Ongoing
Enter +Clean Study Data			Ongoing	Ongoing
Data Analysis				Preliminary
Write and submit results				

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 Goals- Ongoing recruitment and continue to reach for target planned.
Comments/Challenges/Issues/Concerns: Recruitment ongoing at a good pace for the past six months.
 Actual Budget Expenditure III 09/15/2021. \$267,505.16