

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 Inc
Salem VA 24153**

REPORT DATE: October 2018

TYPE OF REPORT: Annual

**PREPARED FOR: U.S. Army Medical Research and Materiel 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 PAGE*Form 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 2018**2. REPORT TYPE**
Annual**3. DATES COVERED**
15-Sept-2017 -14 Sep 2018**4. TITLE AND SUBTITLE:**

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

5a. CONTRACT NUMBER**5b. GRANT NUMBER**
W81XWH-17-1-0326**5c. PROGRAM ELEMENT NUMBER****6. AUTHOR(S)** Mamta Sapra, MD , mamta.sapra@va.gov**5d. PROJECT NUMBER****5e. TASK NUMBER****5f. WORK UNIT NUMBER**

E-Mail:mamta.sapra@va.gov

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)Salem Research Institute Inc
Salem VA 24153**8. PERFORMING ORGANIZATION REPORT****9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)**U.S. Army Medical Research and Materiel 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	19a. NAME OF RESPONSIBLE PERSON USAMRMC
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.....	1
2. Keywords	1
3. Accomplishments.....	1
4. Impact.....	3
5. Changes/Problems.....	3
6. Products.....	4
7. Participants & Other Collaborating Organizations.....	5
8. Special Reporting Requirements.....	6
9. Appendices.....	6

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 approval at both sites (VA Salem and VA Boston). The second major task is to start and continue recruitment and implementation of both interventions.

What was accomplished under these goals?

Below we describe our project milestones for Year 1		
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.
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	Partially Completed	Research Assistants have been hired and trained at the Salem site. We are currently recruiting Research Assistants at the Boston site.
Recruit 22 participants at Salem, VA and Boston, VA	Ongoing/Incomplete	We have recruited 7 participants at the Salem, VA site. Boston VA has had a slower start, because PI at Boston VA was on family leave. As of last month, all the regulatory approvals have been completed. The Boston VA Research Institute (BVARI) also has had change in their leadership and staff in the last few months. Hiring process for a Research Assistant is ongoing and job description are being posted. Prescreening for participants has begun in Boston site.

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 aggressively at VA medical center, Salem Virginia and Boston VA .

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

We had delays in receiving regulatory approval at Boston VA site. Finally, all approvals have been completed last month. Hiring process is ongoing at Boston site. Boston VA Research institute (BVARI) has had change in leadership and staff in the past few months which has led to delays in initiation of hiring process for study personnel. One of the study investigators has reached out to her research collaborators at different campus of VA Boston to advise and help the local site investigator with hiring process. The executive director at Salem Research institute is also communicating with BVARI to expedite the hiring.

Changes that had a significant impact on expenditures

Delays in regulatory approval, ordering of supplies led to some delays in initiation of the study. Reduced recruitment due to these delays has impacted expenditure at Salem site. Recruitment and enrollment has begun and is ongoing. We have good prescreening numbers waiting to be scheduled.

Delays in receiving regulatory approvals at Boston and hiring has had impact on spending at Boston VA site. This was completed last month and hiring process is ongoing. Prescreening has begun.

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 on the development of a mindfulness-based caregiver intervention (PAACC) at Southern regional meeting of Gerontological Society of America (SGSA) in Atlanta.

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: M. Lindsey Jacobs

Project Role: Local Site Investigator (Boston)

Researcher Identifier (e.g. ORCID ID):

Nearest person month worked: 1

Contribution to Project: Dr. Jacobs is the study LSI for Boston VA site.

Funding Support: Dr. Jacobs's salary is supported by Veteran Affairs Medical Center. Dr. Jacobs 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

What other organizations were involved as partners?

-

Nothing to Report

8. SPECIAL REPORTING REQUIREMENTS

See included Quad Chart

9. APPENDICES: See attached Quad chart

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

Insert ERMS/Log Number and Task Title Here

W81XWH-17-1-0326



PI: Mamta Sapra, MD

Org: Salem Research Institute, Inc.

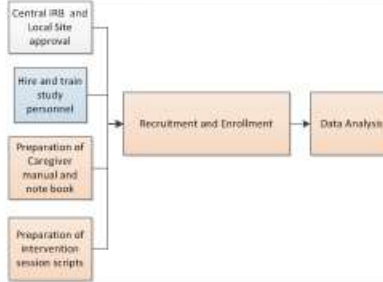
Award Amount: \$485,406

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).



Timeline and Cost

Activities	Year 1	Year 2	Year 3
Regulatory Approvals	█		
Preparatory Tasks	█		
Subject Recruitment	█	█	█
Enter +Clean Study Data		█	█
Data Analysis			█
Write and submit results			█
Estimated Budget (\$k)	\$142.9	\$179.5	\$162.9

Updated: 10/15/2018

Goals/Milestones (Example)

Year 1 Goals – Hire and train study personnel, obtain regulatory approval, Start recruitment

- Central Institutional Review Board approval
- Submitted approvals to HRPO.
- Prepare Caregiver manual, script.
- Begin Recruitment

Year 2 Goals – Continue Recruitment and study intervention

- Complete target recruitment for year 2 and preliminary data analysis

Year 3 Goals – Reach target recruitment and complete study data

- Complete data analysis and prepare manuscripts and reports

Comments/Challenges/Issues/Concerns

- Setting up sub-awards, begin spending

Budget Expenditure to Date

Projected Expenditure: \$71,450

Actual Expenditure: \$36,374.47