

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 24153

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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					
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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 approval at both sites (VA Salem and VA Boston). The second major task is to start and continue recruitment and implementation of both interventions. The Major task for year 2 is ongoing continued recruitment for the trial.

What was accomplished under these goals?

Below we describe our project milestones for Year 1 and Year 2

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.
Recruit 76 participants at Salem, VA and Boston, VA	Ongoing/Incomplete	We have screened 34 participants at Salem site. Out of 34, 1 screen failed, 33 randomized. Boston site has screened 14 participants. Out of 14, 5 participants screen failed, and 9 have been randomized.

At the Salem VA site, ongoing recruitment continues. Prescreening continues and we have several potentially eligible caregivers who have expressed interest in the study. We are also working on submission and approval for possible radio advertisement for the trial. We continue to reach out to different clinics including various primary care clinics, mental health clinics and gero-psychology clinics.

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. We are working on increasing our recruitment efforts at both sites through approvals for advertisement of the study at different clinics as well as radio advertisement. The PI is working with local site investigator at Boston site to remove any barriers and increase recruitment numbers.

4.

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 at this time except much slower pace of recruitment at Boston site. We are behind our target recruitment numbers and are actively working on improving those. The action plan is to continue to share information about the study with more clinics and staff at both sites. Also working on different methods of advertisement about the study after obtaining appropriate Central Institutional review Board approvals. This includes radio advertisement, approval for flyers to be mailed to caregivers, expand recruitment to clinics at different campus of Boston VA.

The PI is planning to go to National Research Summit on Dementia care, Caregiving and Services.

Changes that had a significant impact on expenditures

Delays in regulatory approval and delay in initiation of the study has had impact on difference between planned and actual expenditure. Delays in hiring at Boston has had impact on spending at Boston VA site. The study team is now focused on continued recruitment to meet our target numbers.

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 poster presentation on qualitative data so far is planned for upcoming annual Gerontological Society of America meeting is planned in November in Texas.

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)
W81XWH-17-1-0326



PI: Mamta Sapra, MD

Org: Salem Research Institute, Inc.

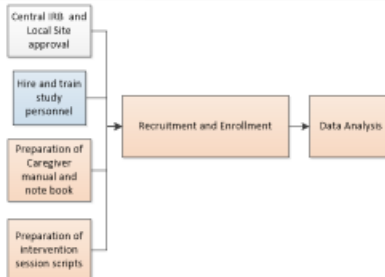
Award Amount: \$485,406

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 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).



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: 10/30/2019

Goals/Milestones

Year 1 Goals -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, but below target numbers.

Year 3 Goals – Reach target recruitment and complete study data

- Complete data analysis and prepare manuscripts and reports

Comments/Challenges/Issues/Concerns: Low recruitment at Boston site. Working on barriers. Increase recruitment efforts by local Boston site team.

Actual Budget Expenditure till 10/30/2019:\$156,394.15