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

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6. AUTHOR(S)

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5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Veteran Affairs Medical
Center, Salem Virginia
1970 Roanoke Blvd, Salem
Virginia 24153

8. PERFORMING ORGANIZATION REPORT

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
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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					
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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 and 3 is ongoing continued recruitment for the trial.

What was accomplished under these goals?

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

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 and randomized 17. Boston site has been closed this year due to move of the investigator.
Recruitment at Salem, VA	Ongoing	Salem is actively recruiting participants. Currently we have 51 enrolled with 49 randomized. We will continue to recruit actively to meet our target.

In year 3, Boston site has been closed due to move of the local site investigator. For the year 3, research activities were on hold due to ongoing COVID-19 pandemic for the past 6months. IRB has approved change to the protocol and given an option of completing study visits virtually through telehealth without changing any structure of the visits including the intervention. We have started recruitment back up slowly and participants are being given choice of in person or virtual study visits. The study team will continue to monitor the pandemic situation and continue to follow the local institutional research guidelines.

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 as the pandemic allows. The approved option of choice of completing visits virtually will also help the team reach their target numbers without changing the intervention. We are also in the process of hiring another interventionist for the project who will help us to have higher number of participants doing intervention at any given time period.

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 due to COVID-19 pandemic. We are lagging behind our target numbers due to low numbers at Boston site at the time of closure. The action plan is to continue to recruit aggressively to make up for lost time due to COVID-19 and low numbers due to Boston closure. We are hiring another interventionist as we are seeing increased interest in the study by the caregivers recently due to COVID-19 pandemic stress. This will help us enroll at higher rate than planned for this remaining study period.We are also planning to use radio advertisement if needed and its already been approved by IRB.

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. We 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 poster presentation on qualitative data has been presented at last year's annual 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.

See included Quad Chart

9. APPENDICES: *See attached Quad chart*

Practice of Acceptance, Awareness, and Compassion in Caregiving (PAACC)
W81XWH-17-1-0326

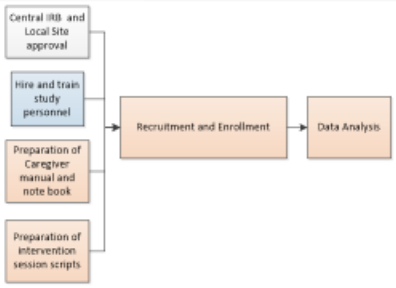
PI: Mamta Sapra, MD **Org:** Salem Research Institute, Inc. **Award Amount:** $485,406

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: 10/31/2020

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.

Year 3 Goals – Reach target recruitment and complete study data - Complete data analysis and prepare manuscripts and reports

Comments/Challenges/Issues/Concerns: Recruitment hold due to COVID-19

Actual Budget Expenditure till 10/31/2020: $220,194.61