

**AWARD NUMBER:** W81XWH-20-1-0441

**TITLE:** Stress Management, Education, Efficacy Building in Dyads Coping with Dementia-Related Symptoms (SEEDS)

**PRINCIPAL INVESTIGATOR:** Mamta Sapra, MD

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

**REPORT DATE:** July 2021

**TYPE OF REPORT:** Annual

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

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# REPORT DOCUMENTATION PAGE

*Form Approved*  
*OMB No. 0704-0188*

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<b>1. REPORT DATE</b> July 2021	<b>2. REPORT TYPE</b> Annual	<b>3. DATES COVERED</b> 01Jun2020-31May2021
<b>4. TITLE AND SUBTITLE:</b> Stress Management, Education, Efficacy Building in Dyads Coping with Dementia-related Symptoms.		<b>5a. CONTRACT NUMBER</b> W81XWH-20-1-0441
		<b>5b. GRANT NUMBER</b>
		<b>5c. PROGRAM ELEMENT NUMBER</b>
<b>6. AUTHOR(S)</b> Mamta Sapra, MD , mamta.sapra@va.gov  E-Mail:mamta.sapra@va.gov		<b>5d. PROJECT NUMBER</b>
		<b>5e. TASK NUMBER</b>
		<b>5f. WORK UNIT NUMBER</b>
<b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b>  Veteran Affairs Medical Center, Salem Virginia 1970 Roanoke Blvd, Salem Virginia 24153		<b>8. PERFORMING ORGANIZATION REPORT</b>
<b>9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)</b>  U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012		<b>10. SPONSOR/MONITOR'S ACRONYM(S)</b>
		<b>11. SPONSOR/MONITOR'S REPORT NUMBER(S)</b>
<b>12. DISTRIBUTION / AVAILABILITY STATEMENT</b>  Approved for Public Release; Distribution Unlimited		
<b>13. SUPPLEMENTARY NOTES</b>		
<b>14. ABSTRACT</b> Cognitive deficits and neurobehavioral symptoms are common in both TBI and dementia and cause varying levels of distress for both the person with dementia (PWD) with the disease and their family caregivers. Stress levels have been associated with dysregulation of cortisol and other biopsychological stress markers in both PWDs and caregivers. There is a growing need to explore the interpersonal and psychosocial benefits of an intervention that considers the collective dementia experience for the dyad. This study offers one such attempt by investigating a mindfulness-enhanced, multicomponent dyad intervention, called SEEDS: Stress management, Education, Efficacy-building, in Dyads coping with dementia related Symptoms. <b>Hypotheses:</b> It is hypothesized that participation in the SEEDS intervention will result in significant improvement in quality of life and health for both the PWD and the caregiver. It is also hypothesized that there will be improved regulation of biomarkers of stress in the dyad after participating in the SEEDS intervention. <b>Specific Aims:</b> 1) To evaluate the effectiveness of a mindfulness-enhanced dyad intervention (SEEDS), that also includes dementia care skill-building components, on quality of life in PWDs and their caregivers, 2) To evaluate the effectiveness of SEEDS on improving biomarkers of stress in PWDs and their caregivers. <b>Research Strategy:</b> We propose a prospective pre-post quasi-experimental design trial, enrolling 165 dyads, to evaluate the effectiveness of a mindfulness-enhanced dyad intervention (SEEDS). Participants will be individuals diagnosed with mild or moderate Alzheimer's disease (AD) and Alzheimer's related dementia (ADRD) and their caregivers. Both caregiver and PWD will complete measures of quality of life, mood, health, stress, mindfulness, and compassion pre and post intervention. Stress markers will also be measured in both caregivers and PWD before and after the intervention. The intervention is six biweekly 75-minute sessions, structured into 30 minutes of a 1:1 session, followed by 45 minutes of a joint session with the dyad. compassion. Pre- and post-treatment assessment measures will be completed by an independent evaluator who will not be providing the intervention. Treatment effects between groups and across time, and interactions will be analyzed using ANOVA and repeated measures GEE. Actor-Partner Interdependence Models will be used to test the effect of each partner's predictors on their own (actor effects) and their partner's outcomes (partner effects).		

<b>15. SUBJECT TERMS</b> Dementia, caregivers, dyad, mindfulness, compassion, clinical trial, intervention					
<b>16. SECURITY CLASSIFICATION OF:</b>			<b>17. LIMITATION OF ABSTRACT</b>  Unclassified	<b>18. NUMBER OF PAGES</b>  9	<b>19a. NAME OF RESPONSIBLE PERSON</b> USAMRMC
<b>a. REPORT</b>  Unclassified	<b>b. ABSTRACT</b>  Unclassified	<b>c. THIS PAGE</b>  Unclassified			<b>19b. TELEPHONE NUMBER</b> <i>(include area code)</i>

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

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## 2. INTRODUCTION:

Cognitive deficits and neurobehavioral symptoms are common in both TBI and dementia and cause varying levels of distress for both the person with dementia (PWD) with the disease and their family caregivers. Stress on the PWD can contribute to ongoing neurodegeneration and worsening of illness-related symptoms. Caregiving stress has been linked to increased risk of psychiatric morbidity and mortality. Stress levels have been associated with dysregulation of cortisol and other biopsychological stress markers in both PWDs and caregivers. Several psychosocial and psychoeducational interventions have been developed that target either the caregiver or the PWD, but there exists a significant gap in the literature on dyadic interventions. Little research exists that explores the potential benefits of incorporating mindfulness in the context of the dementia process, and as a dyad. There is a growing need to explore the interpersonal and psychosocial benefits of an intervention that considers the collective dementia experience for the dyad. Still lacking is a feasible, multicomponent intervention that teaches stress management and self-efficacy skills, focuses on communication, uses mindfulness as collective experience, and uses both subjective and objective measures of stress and quality of life. This study offers one such attempt by investigating a mindfulness-enhanced, multicomponent dyad intervention, called SEEDS: Stress management, Education, Efficacy-building, in Dyads coping with dementia related Symptoms.

## 3. KEYWORDS:

Dementia, caregivers, dyad, self-efficacy, mindfulness, compassion, clinical trial, intervention

## 4. ACCOMPLISHMENTS

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

- . **Specific Aims:** 1) To evaluate the effectiveness of a mindfulness-enhanced dyad intervention (SEEDS), that also includes dementia care skill-building components, on quality of life in PWDs and their caregivers, 2) To evaluate the effectiveness of SEEDS on improving biomarkers of stress in PWDs and their caregivers.

The first major task listed for these goals in SOW for year 1 are hire and train study personnel, obtain regulatory approval. The second major task is to start and continue recruitment and implementation of intervention. 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	Completed	The project has been approved by Veteran Affairs Institution Review Board for Salem. Regulatory approval has been completed and received from DoD Human Research Protection Office. Annual continuing review approvals obtained Institutional Review Board this week as well.
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/person with dementia, and dyad notebooks has been created.
Hire Research Assistant and interventionist.	In process	Positions have been advertised and interviews are being conducted for research interventionist.
Recruitment	Starting this quarter.	The study team has identified 4 potential dyads who are eligible for the study and will start enrolling this quarter.

The study teams aim to start enrollment this quarter and continue recruitment. Local institutional policies now are allowing in person research visits and most of the veterans have been vaccinated.

**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 start recruitment and enrollment this quarter. Also, will finalize the hiring of research interventionist for the trial

**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 at this time except much slower start of the project due to COVID-19 pandemic. We are behind our target numbers but aim to start enrollment this quarter. We don't have local restrictions for research visits anymore.

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

Delays in initiation of recruitment and enrollment as well as hiring of research interventionist has had impact on difference between planned and actual expenditure

**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**

Nothing to report

**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:* Lauren Hageman  
*Project Role:* Co-PI  
*Researcher Identifier (e.g. ORCID ID):*  
*Nearest person month worked:* 1

*Contribution to Project:* Dr. Hageman is the study co-PI.  
*Funding Support:* Dr. Hageman’s salary is supported by Veteran Affairs Medical Center. Dr. Hageman is full time VA employee.

*Name:* Rachael Hartman  
*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:* Through the research Grant.

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

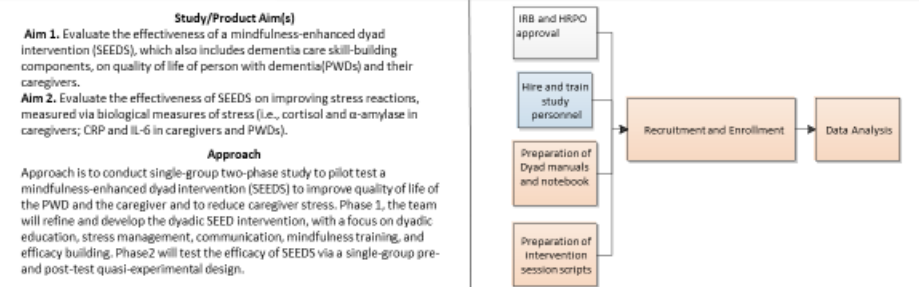
**8. SPECIAL REPORTING REQUIREMENTS**  
See included Quad Chart

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

Stress Management, Education, efficacy-building in Dyads Coping with Deementia-related symptoms (SEEDS)  
W81XWH-17-1-0326



PI: Mamta Sapra, MD      Org: Salem Research Institute, Inc.      Award Amount: \$500,000



**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)	\$157,736	\$163,898	\$178,366

Updated: 06/30/2021

**Goals/Milestones**

- Year 1 Goals** – Hire and train study personnel, obtain regulatory approval, Start recruitment
- Institutional Review Board approval.
  - Prepare Dyad 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**  
Slower start due to COVID-19 pandemic, but plan to start enrollment this quarter.  
Actual budget expenditure till 06/30/2021: \$22,502.54