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

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CONTRACTING ORGANIZATION: Salem Research Institute, Salem, VA

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14. ABSTRACT 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. Hypotheses: 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. 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. Research Strategy: 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).			

15. SUBJECT TERMS Dementia, caregivers, dyad, mindfulness, compassion, clinical trial, intervention					
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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 on 06/12/2023 by Institutional Review Board as well as sent to HRPO.
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.	Completed	Hired research interventionist who has started seeing dyads for the study.
Recruitment	Ongoing	35 dyads have been enrolled, 14 have completed the study and 21 are ongoing with study visits.

The study team aims to continue to enroll and explore different options including advertising outside the VA.

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?

Continue to recruit and enroll participants. Also exploring local approval to enroll some non-veterans to reach out target goal.

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

Continue to work on increased pace of enrollment, this last year has been more successful, Also working on getting approval locally to enroll some number of non-veterans in the study to meet our target. We have the resources and staff but bringing this elderly patient population in person for sessions is difficult with their ongoing physical health issues as well.

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. But now fully staffed and working on faster recruitment.

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.

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

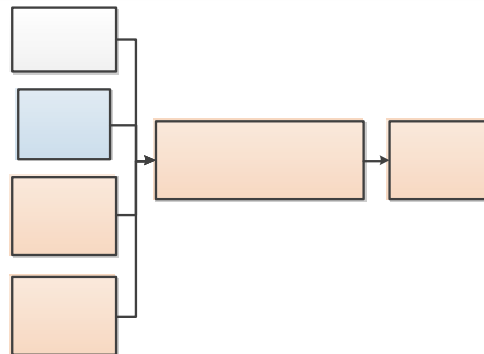
Stress Management, Education, efficacy building in Dyads Coping with Dementiarelated symptoms (SEEDS)
W81XWH-17-1-0326



PI: Mamta Sapra, MD

Org: Salem Research Institute, Inc.

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Timeline and Cost

Acti				
Regulatory Approvals	█			
Preparatory Tasks	█			
Subject Recruitment		█		
Enter +Clean Study Data			█	
Data Analysis				█
Write and submit results				█
Esti				

Updated: 06/30/2023

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

Year 3 Goals– Continue recruitment and try to reach out target numbers.

Complete data analysis and prepare manuscripts and reports

Comments/Challenges/Issues/Concerns

Recruitment ongoing.