

AWARD NUMBER: W81XWH-20-1-0448

TITLE: An Innovative Supportive Care Model for Dementia and Traumatic Brain Injury

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CONTRACTING ORGANIZATION: University of Virginia

REPORT DATE: October 2023

TYPE OF REPORT: Annual

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

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REPORT DOCUMENTATION PAGE

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1. REPORT DATE OCTOBER 2023		2. REPORT TYPE ANNUAL		3. DATES COVERED 1 SEPT 2022 - 31 AUG 2023	
4. TITLE AND SUBTITLE An Innovative Supportive Care Model for Dementia and Traumatic Brain Injury				5a. CONTRACT NUMBER W81XWH-20-1-0448	
6. AUTHOR(S) Dr. Carol Manning, PhD ANNA ARP, CCRP E-Mail: AMH3ZG@HSCMAIL.MCC.VIRGINIA.EDU				5b. GRANT NUMBER	
				5c. PROGRAM ELEMENT NUMBER	
				5d. PROJECT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) RECTOR & VISITORS OF THE UNIVERSITY OF VIRGINIA 1001 N EMMET ST CHARLOTTESVILLE VA 22903-4833				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
				8. PERFORMING ORGANIZATION REPORT	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT 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 During the course of the reporting period, the study team continued to enroll participants into the study. The study is currently in data collection phase with no findings to report at this time.					
15. SUBJECT TERMS Alzheimer's disease and related dementias (ADRD), Behavioral symptoms of dementia (BSD), Best medical treatment (BMT), Dementia care manager (DCM), Informed consent form (ICF), Institutional Review Board (IRB), Legal Authorized Representative (LAR), Memory and Aging Care Clinic (MACC), Mild cognitive disorder (MCI), Major neurocognitive disorder (MND), Person with dementia (PWD), Person with dementia - Alzheimer's disease and related dementias (PWD-ADRD), Person with dementia following a traumatic brain injury (PWD-TBI), Traumatic Brain Injury (TBI)					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRDC
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER (include area code)
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Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

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INTRODUCTION: The Innovative Supportive Care Model for Dementia and Traumatic Brain Injury aims to fill a gap in research through investigation of the efficacy of a nonpharmacological, dementia care coordination program for caregivers of community-dwelling persons with dementia (PWD), delivered via a novel telehealth technology approach. The project examines the program’s efficacy in 1) reducing caregiver burden, 2) reducing symptoms of depression, 3) improving caregivers’ ability to effectively cope with the behavioral symptoms of dementia (BSD), and 4) improving quality of life in caregivers of PWD, particularly those with dementia following a traumatic brain injury (TBI).

KEYWORDS:

1. Alzheimer’s disease and related dementias (ADRD)
2. Behavioral symptoms of dementia (BSD)
3. Benjamin Rose Institute (BRI)
4. Best medical treatment (BMT)
5. Dementia care manager (DCM)
6. Human Research Protection Office (HRPO)
7. Informed consent form (ICF)
8. Institutional Review Board (IRB)
9. Legal Authorized Representative (LAR)
10. Memory and Aging Care Clinic (MACC)
11. Mild cognitive disorder (MCI)
12. Major neurocognitive disorder (MND)
13. Person with dementia (PWD)
14. Person with dementia – Alzheimer’s disease and related dementias (PWD-ADRD)
15. Person with dementia following a traumatic brain injury (PWD-TBI)
16. Standard operating procedures (SOP)
17. Traumatic Brain Injury (TBI)

ACCOMPLISHMENTS:

What were the major goals of the project?

Major Task 1 – Preparation for Intervention	Months	% Complete
Refine BRI Care Consultation Implementation, entry and exclusion criteria	1-2	100
Refine recruitment protocol among recruitment sources	1-2	100
Prepare and submit IRB/HRPO documents	1-3	100
Prepare randomization between BMT and intervention groups	2	100
Develop and finalize CM training modules, to include mixed AD and TBI	1-3	100
Milestone Achieved: Local IRB/IACUC Approval	3	100
Milestone Achieved: HRPO Approval	4	100
Major Task 2 Training		
Develop Training including PWD and caregiver guides specific to the dementia stage and TBI	3	100
Train CM on rating scales	2-3	100
Milestone Achieved: CM training completed	4	100
Milestone(s) Achieved: Launch Care Coordination Program, Begin participant recruitment	4	100
Major Task 3 Preparation for Telehealth		
Develop Telehealth protocol using WebEx platform	2-3	100
Train on Telehealth platform	3	100
Perform 3 “practice” telehealth interviews	4	100
Milestone Achieved: Initiation of Telehealth BRI intervention	5	100
Major Task 4– Intervention/Data Collection		
Enter participants in intervention and BMT groups	4-22	100
Completion of intervention	32	93

Major Task 4 Data Analysis and Data Dissemination		
Data Monitoring and Cleaning	4-36	84
Statistical Analysis	32-36	0
Data Interpretation	32-36	0
Manuscript and abstract preparation, final report	36	0
Milestone Achieved: Dissemination of findings at National Meetings and DOD	32-36	0
Milestone Achieved: Publication of abstracts and manuscripts	36	0

What was accomplished under these goals?

INTERVENTION/DATA COLLECTION: ENTERING PARTICIPANTS

Since the beginning of the study, 169 dyads have been enrolled, accounting for 121% of the overall study recruitment goal. Of the 169 dyads enrolled, 129 enrolled into the ADRD arm, accounting for 129% of the ADRD recruitment goal, and 40 enrolled into the PWD-TBI arm, accounting for 100% of the TBI recruitment goal. The study team overenroll in the ADRD arm consistent with the decision made previously to account for participants withdrawing from the study.

During the reporting period, 44 dyads completed the intervention and 40 of those dyads completed 12-month questionnaires. In the BMT group, 50 dyads completed the 12-month questionnaires and have rolled over into the intervention. To date, in all groups 131 participants have completed intervention and/or 12-month assessments.

To date, 40 participants have withdrawn from the ADRD arm and 9 participants have withdrawn from the TBI arm. Out of the 49 participants withdrawn, 17 participants had received intervention. Regarding reasons for withdrawing from the study, 17 participants passed away, 12 participants moved to a higher level of care, 4 participant moved out of state, 11 participants stopped communication with the study team, and 5 participant chose to withdraw from the study.

DATA ANALYSIS AND DATA DISSEMINATION: DATA MONITORING

During the reporting period, the study team entered and managed data on the 169 dyads enrolled in the study. The study coordinator maintains the REDCap database, ensuring that each dyad has completed the baseline, 12-month, and follow-up questionnaires as they become applicable. The biostatistician is responsible for data analysis and ensuring the randomization strategy.

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?

During the upcoming reporting period, the study team will continue to provide intervention according to the protocol. The study team will continue to maintain the REDCap database and work with participants to complete questionnaires as they become applicable. The study team plans to conclude data monitoring and cleaning in the next year and will start statistical analysis and data interpretation.

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

CHANGES/PROBLEMS:

Changes in approach and reasons for change

The study team requested and received a one year extension of the grant to allow for all participants to complete intervention and follow up.

Actual or anticipated problems or delays and actions or plans to resolve them

During the reporting period, the study team faced challenges with participant compliance in completing questionnaires. The study team developed new procedures to increase compliance by monitoring questionnaire completion more closely and contacting participants in a timely manner. Repeated contacts and reminders has increased compliance.

Changes that had a significant impact on expenditures

Nothing to Report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents.

Nothing to Report.

Significant changes in use or care of human subjects

Nothing to Report

Significant changes in use or care of vertebrate animals.

Not Applicable

Significant changes in use of biohazards and/or select agents

Not Applicable

PRODUCTS:

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.

PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name: Dr. Carol Manning, Ph.D.

No change from quarter 3 report.

Name: Elizabeth Boyd

No change from quarter 3 report.

Name: Samantha Fields

No change from quarter 3 report.

Name: Anna Arp

No change from quarter 3 report.

Name: James Patrie

No change from quarter 3 report.

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?

Organization Name: Alzheimer's Association

Location of Organization: Richmond, VA

Partner's contribution to the project: Collaboration and personnel exchange - The Alzheimer's Association has contributed a Dementia Care Manager, Jessica Samet, to the study team. The Association offices and staff have been available to provide resources to assist clinic patients and their caregivers. Ms. Samet maintains relationships with personnel at the Association and communicates regularly with them regarding initiatives and services available. Ms. Samet brings an in-depth knowledge of the Alzheimer's Association's services to the team and keeps the team informed of new initiatives offered by the Association.

Organization Name: Aging Together

Location of Organization: Culpeper, VA

Partner's contribution to the project: Other - Partner provides local community resource list, and also shares information on relevant local community partners that provide respite funds for a family in the project.

Organization Name: All Blessings Flow

Location of Organization: Culpeper, VA

Partner's contribution to the project: In Kind Support: Partner provides CC's free recycled durable medical equipment to distribute to families in the project.

Organization Name: JABA

Location of Organization: Culpeper, VA

Partner's contribution to the project: Collaboration: Care Coordinators refer families to this area agency on aging for options counseling support. JABA then sends Options Counselors to patient's homes to identify other supplementary programs they may qualify for (i.e. home deliver meals and local weatherization programs).

Organization Name: Doris Gelbman – local elder law attorney

Location of Organization: Culpeper, VA

Partner's contribution to the project: Other- Partner provides Care Coordinator with information on Medicaid spend down to share with family in the project.

Organization Name: Drew Yeannakis

Location of Organization: Culpeper, VA

Partner's contribution to the project: Other- Partner provides information to Care Coordinators about disability applications and appeals process to share with patients and caregivers.

Organization Name: Department of Aging and Rehabilitative Services

Location of Organization: Culpeper, VA

Partner's contribution to the project: Other- Partner provides state respite funds that Care Coordinators are able to share with caregivers in the project.

SPECIAL REPORTING REQUIREMENTS

QUAD CHARTS: Submitted with this report.

APPENDICES:

**APPENDIX A.
Enrollment Tables**

Study Arm/Group	Target Enrollment	Total Enrolled	% of Target
Overall Recruitment	140	169	121%
ADRD Arm	100	129	129%
Intervention Group	50	46	92%
BMT Group	50	43	86%
Withdrawn		40	
TBI Arm	40	40	100%
Intervention Group	20	14	70%
BMT Group	20	17	85%
Withdrawn		9	

Study Arm/Group	Participant Study Status				
	Receiving Intervention	Waiting for Intervention	In Follow-up	Completed Study	Withdrawn
ADRD Arm	34	0	22	34	39
Intervention Group	2	N/A	11	34	16
BMT Group	32	0	11	0	23
TBI Arm	13	4	10	5	8
Intervention Group	0	N/A	9	5	4
BMT Group	13	4	1	0	4
Totals	47	4	32	39	47