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

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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)					
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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	14

Major Task 4 Data Analysis and Data Dissemination		
Data Monitoring and Cleaning	4-36	35
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

Between September 1 2021 and August 31 2022, 123 dyads were randomized into the study with 35 enrolled into the PWD-TBI arm and 88 enrolled into the PWD-ADRD arm. Of the 35 PWD-TBI participants 14 randomized into the intervention group, 17 randomized into the BMT group, and 4 withdrew from the study. These 35 dyads account for 88% of the recruitment goal for the PWD-TBI arm of the study. Of the 88 dyads enrolled into the PWD-ADRD arm 43 randomized to the BMT group, 36 randomized to the intervention group, and 9 withdrew from the study. These 88 dyads account for 88% of the recruitment goal for the PWD-ADRD arm of the study.

Since the beginning of the study 170 dyads have been enrolled, accounting for 121% of the overall study recruitment goal. Of the 170 dyads enrolled, 130 enrolled into the ARDR arm, accounting for 130% of the recruitment goal, and 40 enrolled into the PWD-TBI arm, accounting for 100% of the recruitment goal. The study team continued to overenroll in the ARDR arm consistent with the decision made previously to account for participants withdrawing from the study.

To date, 16 participants have withdrawn from the ARDR arm and 4 participants have withdrawn from the TBI arm for a total of 20 participants withdrawn. Out of the 20 participants withdrawn, 10 participants had received intervention. Regarding reasons for withdrawing from the study, 8 participants passed away, 5 participants had moved to a higher level of care, 1 participant moved out of state, 3 participants stopped communication with the study team, and 3 participant chose to withdraw from the study.

During the reporting period, 24 dyads completed the intervention and 21 dyads completed the 12-month questionnaires. Of the dyads in the BMT group, 17 completed the 12-month questionnaires and have rolled over into the intervention.

DATA ANALYSIS AND DATA DISSEMINATION: DATA MONITORING

During the reporting period, the study team entered and managed data on the 170 dyads enrolled in the study. The study coordinator maintains the REDCap database, ensuring that each dyad has completed the initial set of questionnaires and 12-month 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.

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

During the reporting period, the study team determined that there was a significant TBI patient population that was being overlooked for recruitment. From recruitment efforts and discussions with health care providers, the study team expanded the PWD-TBI inclusion criteria to include diagnosis of Mild Neurocognitive Disorder resulting from the TBI and to include patients having experienced a TBI at or after the age of brain maturity, 25 years of age. The modifications were submitted to the local IRB on 26 January 2022 and 31 March 2022 and were approved by the board respectively on 2 February 2022 and 12 April 2022. The modification approvals were then submitted to the HRPO for approval on 23 March 2022 and 12 April 2022.

An additional revision to the protocol during the 26 January 2022 modification included expansion of enrollment numbers to account for both members of the dyad, PWD and caregiver, signing consent forms.

The study team also developed new procedures and protocols for collecting a final set of questionnaires from participants who terminate early for a variety of reasons, including moving to higher level of care and death of a participant. Procedures were also developed for how to address changes in caregivers and consenting new caregivers participating in the study. These were approved by the IRB on 22 March 2022 and 12 April 2022 and reported to the HPRO for approval on 23 March 2022 and 12 April 2022.

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

Obstacles to recruitment of dyads for the PWD-TBI arm of the study continued to be an area of concern for the study team. The changes to the protocol increased the recruitment pool of patients for this arm of the study and the subsequently the TBI recruitment goals was met.

During the reporting period, the DCMs have found that when the primary caregiver changes in a dyad, the continuity and provision of care becomes more challenging. Similarly, changes in the status of the PWD, including moving to a higher level of care, becoming ill, or passing away, have significant impacts on caregivers and the care coordination DCMs can provide. DCMs have also found that caregiver health status and access to resources plays a large role in their ability to provide care for their loved one. The study team developed protocols and procedures for handling

these challenges to ensure that data can be collected and analyzed appropriately from participants in these situations.

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: Shannon Reilly
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 Table**

Study Arm/Group	Target Enrollment	Total Enrolled	% of Target
Overall Recruitment	140	170	121%
ADRD Arm	100	130	130%
Intervention Group	50	53	106%
BMT Group	50	61	122%
Withdrawn		16	
TBI Arm	40	40	100%
Intervention Group	20	16	80%
BMT Group	20	20	100%
Withdrawn		4	