AWARD NUMBER: W81XWH-22-1-0765

TITLE: Minds Navigating the Diagnosis of Mild Cognitive Impairment (MIND-MCI): Feasibility and Acceptability of a Primary Care Telehealth Intervention

PRINCIPAL INVESTIGATOR: Dr. Patricia Pilkinton

CONTRACTING ORGANIZATION: Tuscaloosa VA Medical Center

REPORT DATE: August 2023

TYPE OF REPORT: Annual Report

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

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
AUGUST 2023	Annual report	1AUG2022 - 31JUL2023

4. TITLE AND SUBTITLE

Minds Navigating the Diagnosis of Mild Cognitive Impairment (MIND-MCI): Feasibility and Acceptability of a Primary Care Telehealth Intervention

5a. CONTRACT NUMBER
W81XWH-22-1-0765

5b. GRANT NUMBER
AZ210020

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

Patricia Pilkinton, MD and Mary Lindsey Jacobs Dodson, PhD.

E-Mail: patricia.pilkinton@va.gov

5d. PROJECT NUMBER
0011752071

5e. TASK NUMBER

5f. WORK UNIT NUMBER

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

Tuscaloosa Research and
Education Advancement (151)
Corporation 3701 Loop Rd E,
Tuscaloosa, AL 35404

8. PERFORMING ORGANIZATION REPORT NUMBER

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

Mild Cognitive Impairment (MCI) affects up to 26% of adults age 60 and older[1] and progresses to dementia at a rate of 12% per year. Multiple modifiable risk factors may change this trajectory. The purpose of this study is to test the feasibility, acceptability, and preliminary effectiveness of a 9 session group telehealth intervention vs waitlist control in addressing modifiable risk factors. Veteran's age 60 and over (N=160)with MCI and at least one cardiovascular risk factor will be recruited from 2 VA medical centers to participate. Subjects will complete measures of cognitive function, physical status, and emotional state at baseline, following the intervention, and at 3 months after the intervention. Acceptability of the intervention will be assess using qualitative and quantitative measures. Primary Care staff will be asked to review and provide feedback on the intervention and modules to facilitate future implementation in primary care settings. Enrollment is anticipated to start in September 2023. No results are yet available.

15. SUBJECT TERMS

Mild Cognitive Impairment, MCI, dementia, cardiovascular risk, telehealth, group intervention, cognition, Veteran

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRDC
U	U	U	UU	11	19b. TELEPHONE NUMBER *(include area code)*

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

TABLE OF CONTENTS

1. INTRODUCTION: *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

Mild Cognitive Impairment (MCI) affects up to 26% of adults age 60 and older[1] and progresses to dementia at a rate of 12% per year. Research has identified multiple modifiable risk factors associated with MCI and dementia. MiND-MCI is a group telehealth intervention targeting cognitive functioning, psychosocial well-being, and lifestyle risk factors through education and training on compensatory and restorative cognitive strategies, coping skills, and health behavior self-management techniques. The purpose of the study is to test the feasibility, acceptability, and preliminary effectiveness of the nine-session MiND-MCI group telehealth intervention in older Veterans with MCI, cardiovascular risk factors, and MCI related distress.

2. KEYWORDS: *Provide a brief list of keywords (limit to 20 words).*

Mild Cognitive Impairment, MCI, dementia, cardiovascular risk, telehealth, group intervention, cognition, Veteran

3. ACCOMPLISHMENTS: *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?
List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Aim 1. Conduct a pilot randomized controlled trial of the MiND-MCI group telehealth intervention to evaluate feasibility, acceptability, and preliminary effectiveness on QoL in older Veterans with MCI, cardiovascular risk factors, and MCI-related psychological distress.

- Prepare regulatory documents and research protocol (Y1, Q3): 100% complete
- Hire and train study personnel (Y1, Q3): 100% complete
- Conduct pilot randomized controlled trial of MiND-MCI vs waitlist (Y1, Q3 to Y3, Q3) 0%, anticipated start of enrollment August-Sept 2023
- Analyze data and disseminate findings (Y2, Q1 to end of study): 0% complete

Aim 2. Explore PC-MHI providers' perceptions of MiND-MCI to identify potential modifications that will improve its quality and overall feasibility of delivery in primary care.

- Gather quantitative and qualitative data from PC-MHI providers (Y2, Q3 to Y3, Q2): 0% complete
- Analyze data and disseminate findings (Y3, Q2 to end of study): 0% complete

What was accomplished under these goals?
For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Aim 1. Randomized Controlled Trial

- Prepare regulatory documents and research protocol
    - Regulatory documents were prepared, submitted to VA CIRB, and received approval on May 4, 2023. R&D Committee approval was obtained on June 29, 2023.
    - Local site applications to VA CIRB submissions for Tuscaloosa and Salem occurred in June 2023
        - Salem VAMC was approved on June 22, 2023 and local R&DC approval obtained on July 26, 2023
        - Tuscaloosa VAMC was approved on August 3, 2023 and local R&DC approval obtained on August 28, 2023.
    - Registration with Clinical Trials.gov was obtained in January 2023 (NCT 05690243)
    - Regulatory documents were uploaded to eBRAP to OHRO review in June and July 2023.
    - DART data request in July 2023 for updated list of potential subjects from Corporate Data Warehouse.

- Hire and train study personnel
    - Tuscaloosa and Salem Research Coordinators hired onboarded and trained. A back up coordinator has been identified at Tuscaloosa and was being added to the study in August 2023.
    - Weekly study meetings/huddles throughout the first year
    - Study Start-up/Protocol Meeting took place on June 27, 2023 (recorded) Covered protocol, schedule of events, recruitment and screening, enrollment, randomization, assessment tools and scales, telehealth.
    - Interventionist Manual developed, refined, reviewed and approved by CIRB on July 28, 2023.
    - Interventionist training developed and presented on July 27, 2023 (recorded)
    - Participant Workbook developed, adapted to study population, reviewed and approved by CIRB on July 28, 2023. Initial printing July 2023.
    - Back-up Interventionist identified for Tuscaloosa site and in process of onboarding in August 2023.

- Conduct pilot randomized controlled trial of MiND-MCI vs waitlist
    - Recruitment plan, goals, strategy developed; advertising approved by VA CIRB
    - VA Redcap Database developed and ready for production mode
    - Assessment Scales formatted for study population
    - Fidelity assessment methods developed
    - Audio-recording software installed on clinical computers to facilitate fidelity monitoring

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Training:

- Study coordinators received training on VA Redcap development and use through mentorship and self-study
- Interventionist Training Session provided for advancing knowledge of the study intervention (mindfulness, ACT based and telehealth therapies) and uniqueness of delivering therapy to the geriatric population.
- Study staff were provided training and mentorship with Dr's Luci and Jacobs on conducting assessment scales (MOCA and others)

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to Report

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

Primary objective in the coming year is successful recruitment and implementation of the study intervention and assessments. In preparation, we have identified and trained key staff, have prepared all materials and scales, and developed multi-pronged recruitment plan. We are working to identify back-up interventionists and cross train staff between sites.

4. **IMPACT:** D*escribe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

The team has reworked and refined the participant workbook and interventionist manual so that it is user-friendly and can be disseminated rapidly if this intervention is effective.

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report

What was the impact on technology transfer?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Nothing to Report

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report

5. CHANGES/PROBLEMS: *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

Changes in approach and reasons for change
Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Nothing to Report

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

The primary delays we have encountered have been external (obtaining IRB approval). Teams meetings with IRB liaisons and IT have been beneficial in resolving these issues.

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

No significant changes noted.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

No significant changes.

Significant changes in use or care of vertebrate animals

No significant changes.

Significant changes in use of biohazards and/or select agents

No significant changes. No biohazards noted in this study

6. PRODUCTS: *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

Publications, conference papers, and presentations

Report only the major publication(s) resulting from the work under this award.

Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report

Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to Report

Website(s) or other Internet site(s)

List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to Report

Technologies or techniques

Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Nothing to Report

Inventions, patent applications, and/or licenses

Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to Report

Other Products

Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- *data or databases;*
- *physical collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

MIND-MCI Participant Workbook and Intervention Manual were developed and refined.
Training materials (video recording) of the Study Protocol Review and Interventionist training were created.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

Name: **Patricia Pilkinton, MD**
Project Role: PI Project lead, Tuscaloosa VAMC
Research Identifier: N/A
Nearest person month worked: 1.0 person month
Preparation of IRB and ORHO, reports, hiring /supervision of CRC Tuscaloosa, data requests, scale development.

Name: **Mary Lindsey Jacobs, PhD, MSPH**
Project Role: PI, University of Alabama
Research Identifier: 0000-0001-6309-0320
Nearest person month worked: 1.0 person months
Preparation of ICF, IRB, protocol, interventionist manual, staff training, fidelity monitoring

Name: **Katherine Luci, PsyD**
Project Role: PI, Salem VA Medical Center
Research Identifier: 0000-0002-3888-3115
Nearest person month worked: 1.0 person months
Preparation and coordination of IRB submission, interviewing/hiring of CRC Salem, interventionist manual development

Name: **Deanna Dragan, PhD**
Project Role: Interventionist, Salem VA Medical Center
Research Identifier: N/A
Nearest person month worked: 1.0 person months
Development of Interventionist Manual, staff training on intervention

Name: **Allyshia Hinton**
Project Role: Clinical Research Coordinator, Tuscaloosa VA Medical Center
Research Identifier: N/A
Nearest person month worked: 2.0 person months
Redcap database construction, meeting coordination, DART request, Case report form creation

Name: **Steven Kutsch**
Project Role: Clinical Research Coordinator, Salem VA Medical Center
Research Identifier: N/A
Nearest person month worked: 2.0 person months
Redcap database construction, meeting coordination, Case report form creation

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Pilkinton changes:

KOR Antagonism for the Treatment of Alcohol Use Disorder and Comorbid PTSD (now completed)

Role of Environmental Stressors on Veterans Neurocognitive Aging (starting spring 2023)

Clinical effort for MH was returned to 50% effort (temporarily increased to 60% during COVID pandemic).

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Nothing to Report

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to* ***https://ebrap.org/eBRAP/public/index.htm*** *for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on https://www.usamraa.army.mil/Pages/Resources.aspx) should be updated and submitted with attachments.*

9. APPENDICES: *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*