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TITLE: **Effectiveness of a Driving Intervention on Safe Community Mobility for Returning Combat Veterans**

PRINCIPAL INVESTIGATOR: **Sherrilene Classen, PhD, MPH, OTR/L, FAOTA, FGSA**

CONTRACTING ORGANIZATION: **University of Florida**

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14. ABSTRACT Intervention for combat veterans' driving safety requires a multi-factorial approach to address the often co-occurring effects of TBI/ PTSD/ other blast related injuries sustained by combat veterans as well as the impact of deployment experiences on their driving. Intervention provides critical information on the combat veterans' driving fitness, impact of medical and psychological conditions on driving, and driving rehabilitation needs. Effective driving interventions have potential to increase driving safety and reduce MVC and the resulting injuries and deaths. Furthermore, promoting driving fitness may also have carryover effects supporting other key arenas of community re-integration such as family functioning, employment, participation in society, and satisfaction with life. In our efficacy study we demonstrated the feasibility of our intervention, and early data suggest efficacy of the OT-DI for combat veterans with mild TBI, PTSD, and/or orthopedic conditions. The efficacy study did however have limitations including a small sample, attrition, and mostly male subjects. In our current effectiveness study we are seeking to expand our study sample, providing power for more detailed analyses of OT-DI outcomes include reduction of driving errors (measured via simulated driving evaluation), as well as real world outcomes. Ours is the first study to look at impact of an occupational therapy driving intervention on driving difficulty and driving fitness as measured in an on-road evaluation. Additional measures include proxy report of Veteran driving difficulty, and violations, citations, and crashes based on state department of motor vehicle records.					
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Introduction

Intervention for combat veterans' driving safety requires a multi-factorial approach to address the often co-occurring effects of TBI/ PTSD/ other blast related injuries sustained by combat veterans as well as the impact of deployment experiences on their driving. Intervention provides critical information on the combat veterans' driving fitness, impact of medical and psychological conditions on driving, and driving rehabilitation needs. Effective driving interventions have potential to increase driving safety and reduce MVC and the resulting injuries and deaths. Furthermore, promoting driving fitness may also have carryover effects supporting other key arenas of community re-integration such as family functioning, employment, participation in society, and satisfaction with life. In our efficacy study we demonstrated the feasibility of our intervention, and early data suggest efficacy of the OT-DI for combat veterans with mild TBI, PTSD, and/or orthopedic conditions. The efficacy study did however have limitations including a small sample, attrition, and mostly male subjects. In our current effectiveness study we are seeking to expand our study sample, providing power for more detailed analyses of OT-DI outcomes include reduction of driving errors (measured via simulated driving evaluation), as well as real world outcomes. Ours is the first study to look at impact of an occupational therapy driving intervention on driving difficulty and driving fitness as measured in an on-road evaluation. Additional measures include proxy report of Veteran driving difficulty, and violations, citations, and crashes based on state department of motor vehicle records.

Keywords: Randomized Clinical Trial, Intervention, Driving, Rehabilitation, Simulation

ACCOMPLISHMENTS

- Enrolled 37 subjects in the study
- Completed testing with 16 subjects
- Have 10 subjects who are active (baseline testing/ and or additional sessions complete with future testing pending)
- Developed new community partners for recruitments through events.
- Outreach to VA partners across the North Florida / South Georgia VHS service area.
- Dissemination through publications listed below, and citations by additional authors across several fields of study.
- Trained two additional driver rehabilitation specialists to conduct the testing and intervention protocol.
- Trained two persons in implementation of traffic safety education curriculum.
- Technology transfer of visual search strategy training to Drive Focus application.
- Next stage plans – for Year 6 to complete testing and related analyses of intervention effectiveness as well as real-world outcomes (violations, citations, and crashes).
- Additional future work – we were awarded a study from VA Office of Rural Health to implement aspects of the intervention with rural Veterans in a workshop type format, including use of visual search strategy training and use of simulator. Study is in IRB/VA approval for late summer 2020 start.

Impact

On principal discipline – We have been successful at dissemination of a protocol for use of the simulator as a rehabilitation tool for veterans experiencing driving difficulty. In addition to articles, and a book chapter – we have presented at national conferences including those devoted to driving rehabilitation – and our work has been cited in multiple occupational therapy and rehabilitation journals.

On other disciplines - Several disciplines that engage in community reintegration of veterans benefit as our work complements work they are engaged with to address driving difficulty. These disciplines

include but are not limited to psychology, social work, and community service coordinators. Our work also intersects with work done by VA researchers on unintentional injury and prevention. Our work has been cited in publications from mental and behavioral health, public health, social work, rehabilitation counseling, engineering, virtual reality, neuropsychology, and community reintegration among others.

On technology transfer - The newly created simulator drive content is Veteran-centric, addressing driving difficulties unique to this population. Development of this content now makes it available to multiple military and VA sites using the DriveSafety simulators for rehabilitation. New this year, this visual training program has evolved into an application called DriveFocus, with early research demonstrating benefits of app use for enhancing driving fitness. DriveFocus will be used as part of community based intervention on driving and community mobility funded by the VA Office of Rural Health through the new VA Veterans Rural Health Resource Center – Gainesville.

On society – A desired outcome of this work would be, that by addressing driving difficulty in post-deployed veterans, they would be more mobile within their communities. In addition, by reducing driving errors we expect that veterans will have a greater level of safety, and a reduced burden of crashes, unintentional injury, and other negative sequelae.

Changes/Problems - Due to an initial 18 month delay in IRB approval, and low recruitment, we have not met our target sample size at end of year 5. Given year 5 progress in areas including recruitment, dissemination, technology transfer, and use of study findings to create new programs and funded research – we were approved for a Year 6 No Cost Extension. We are on a study hold for COVID-19 (from directives of University of Florida Health Science Center /Research, UF College of Public Health and Health Professions, and National VA - but are active with analyses and manuscript writing. We submitted a research resumption plan to the VA Research Committee on June 10, 2020 (attached) – which is pending review and approval. UF Health Science Center approval for clinical research is happening in phases, studies with direct contact may be given approval to resume July 2020.

Products

Publications: * indicates attached in Appendix A

a) Publications

- i. *Winter, S., Jeghers, M., Reid, E., McGowan, C., Young, M. E., & Classen, S. (2020). Driving outside the wire: Examining factors impacting Veterans' post-deployment driving. *OTJR: Occupation, Participation and Health*. doi: 10.1177/1539449220914533
- ii. Clark, K. (2019) Comparative case-study analysis: Examining driving error differences among male and female veterans post-deployment. (Undergraduate thesis). University of Florida. Gainesville, FL.

b) Publications in preparation/ or reviewed pending re-submission (_____ indicates trainees)

- i. Classen, S., Winter, S. M., King, L. C., Jeghers, M., Wersal, J., Medhizadah, S. & Yarney, A. Developing an occupational therapy driving manualized intervention for returning combat Veterans. Manuscript in preparation for *OTJR: Occupation, Participation and Health*. Anticipated submission date 15 June 2020
- ii. *Classen, S., Winter, S. M., Caldwell, K., Brumback, B., Medhizadah, S., ...Ellison, C. Intervention fidelity: strategies for increasing rigor in a driving intervention randomized clinical trial. Manuscript in preparation for *OTJR: Occupation, Participation and Health*. Anticipated submission date 30 June 2020

- iii. *Classen, S., Yarney, A., & Winter, S. Simulated driving errors as indicators of real world driving events in returning combat veterans. *Reviewed in Fall 2019 by PLOS One Veteran Channel, under revision.*
- iv. Classen, S., Wersal, J., King, L., & Rogers, J. Simulator sickness: An analysis of driving simulation exposure in returning combat Veterans. Manuscript in preparation for *Transportation Research Part F: Traffic Psychology and Behaviour*. Anticipated submission date 30 August 2020.
- v. Medhizadah, S., Ellison, C., Jeghers, M., King, L., Poojary, P., Wersal, J., Winter, S., Classen, S. State-approved traffic safety education intervention for returning combat Veterans: An interim analysis. Manuscript in preparation for *Journal of Safety Research*. Anticipated submission date 27 November 2020

Presentations:

- i. Clark, K., Winter, S., Jeghers, M., & Yarney, A. (2019, November). Comparative case-study analysis: Examining driving error differences among male and female veterans post-deployment. Poster session presented at the Annual Florida Occupational Therapy Association Conference, Orlando, FL.
- ii. Clark, K., Winter, S., Jeghers, M., & Yarney, A. (2019, April). Comparative case-study analysis: Examining driving error differences among male and female veterans post-deployment. Poster session presented at the University of Florida Public Health and Health Professions Research Day, Gainesville, FL.

Participants and other collaborating organizations

Veterans Affairs is a collaborator on this study. The VA Center of Innovation on Disability and Rehabilitation Research, a VA Center of Innovation, ended its 5 year cycle October 2019. A new center, the VA Veteran Rural Health Resource Center – Gainesville started Fall 2019 and they will be a partner with us. The VA provides infrastructure and support for the investigators, material resources such as the simulator, use of VA facilities for recruitment and testing, and research oversight.

During this year, the following persons were active on the project:

Name: Sherrilene Classen, PhD, MPH, OTR/L, FAOTA, FGSA

Project Role: PI as of March 2018 IRB approval

Researcher Identifier (e.g., ORCID ID):

Nearest person month worked: 3

Contribution to Project: Dr. Classen contributed her expertise in clinical trials, guiding study design and implementation, and planning and overseeing the analyses in conjunction with the PI, the biostatistician and co-investigators. Dr. Classen contributed extensively to the development of manuscripts, the submission of presentations, dissemination of findings, and development of future proposals to extend the work. Funding Support: Detailed below

Name: Sandra Winter, PhD, OTR/L

Project Role: PI until March 2018, Co-I after March

Researcher Identifier: orcid.org/0000-0002-0317-241X

Nearest person month worked: 6

Contribution to Project: Dr. Winter had overall responsibility for the project execution. She organized the research team and oversaw main research functions. Thus, appoint research staff, obtain IRB approval, manage developmental activities and research activities, collaborate with the project

personnel, consultant(s), and the developer of the DriveSafety 250 driving simulator. She supervised the research coordinator, research therapist and research assistants, oversaw data collection, analysis and interpretation, and developed manuscripts, research presentations and reports.
Funding Support: Additional project funded by Florida Department of Transportation

Name: Charles Levy, MD

Project Role: Co-I

Researcher Identifier (e.g., ORCID ID):

Nearest person month worked: 1

Contribution to Project: Dr. Levy's functions as a co-investigator include assisting with recruitment, guiding interaction with VA partners, and educating the team on the rehabilitation needs of the returning combat Veterans. He will participate in recruitment of participants, interpretation of the results, outcome dissemination, and translation of study findings to VA health care settings.

Funding Support: Dr. Levy is a VA physician, salary (5% effort) is paid by VA.

Name: Abraham Yarney, M.E.

Project Role: Graduate Student through August 2019. Continuing as WOC status

Researcher Identifier (e.g., ORCID ID): N/A

Nearest person month worked: 6

Contribution to Project: Primary functions are preparation of study materials for recruitment and testing, recruitment, and data entry. Secondary functions are data management, data audits (with PI), and data analysis overseen by the team and the biostatistician.

Funding Support: Only DOD study funding

Name: Mary Jeghers, MSOT, OTR/L

Project Role: Graduate Student

Researcher Identifier (e.g., ORCID ID): N/A

Nearest person month worked: 3

Contribution to Project: Primary functions are preparation of study materials for recruitment and testing, distribution of recruitment materials, and data entry. Secondary functions are data management, data audits (with PI), and analysis of data as overseen by the team and the biostatistician.

Funding Support: Additional project funded by Florida Department of Transportation

Name: Shabnam Medhizadah, MS

Project Role: Graduate Student

Researcher Identifier (e.g., ORCID ID): N/A

Nearest person month worked: 5

Contribution to Project: Primary functions are preparation of study materials, screening participants, recruitment, and participant payment.

Funding Support: Additional project funded by Florida Department of Transportation

Name: Kasey Clark

Project Role: Research Assistant / Other Personnel Services status

Researcher Identifier (e.g., ORCID ID): N/A

Nearest person month worked: 3

Contribution to Project: Primary functions are preparation of study materials for recruitment and testing, distribution of recruitment materials, and data entry.

Funding Support: N/A

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period? Yes, Dr. Sherrilene Classen's current support for additional projects is listed below:

U.S. DOT and UF Transportation Institute Total Cost: \$220,000 March 2020–Sept. 2021

Role: Principal Investigator

UF and UAB's Phase 2 Demonstration Study: Developing a Model to Support Transportation System Decisions Considering the Experiences of Drivers of All Age Groups with Autonomous Vehicles

Goal: Build a predictive model of drivers (all ages) perceptions of autonomous vehicles.

Florida Department of Transportation Total Costs: \$174,000 Oct. 2019–Sept. 2020

Role: Principal Investigator

Aging Road User Information Systems

Goal: Enhance the Florida Senior Safety Resource Center's database with GIS mapping.

U.S. DOT and UF Transportation Institute Total Cost: \$220,000 Aug. 2018–Sept. 2020

Role: Principal Investigator

Older Drivers' Experiences with Autonomous Vehicle Technology

Goal: Quantify the older drivers' perceptions before and after exposure to autonomous vehicles.

Florida Department of Transportation Total Cost: \$469,000 June 2019–June 2021

Role: Co-Principal Investigator

Transportation Mobility Assessments and Recommendations for Smart City Planning

Goal: Develop and test a community-based participatory methodology for developing transportation mobility plans by assessing the needs of travelers in Florida neighborhoods.

Paralyzed Veterans of America Total Cost: \$50,000 June 2019–Dec. 2020

Role: Principal Investigator

Perceptions of Individuals with Spinal Cord Injury/Disease Regarding Autonomous Vehicles

Goal: Elucidate the perceptions of those with a spinal cord injury/disease before and after riding in an autonomous shuttle.

What other organizations were involved as partners?

1) Organization Name: Veteran Affairs / North Florida – South Georgia VHS

Location of Organization: Gainesville, Florida

Partner's contribution to the project:

- Financial support provided for Dr. Levy's salary and expenses for simulator van (insurance, fuel and maintenance)
- In-kind support is provided through use via revocable license of two DriveSafety simulators
- Facilities support includes use of office space at Center of Innovation on Disability and Rehabilitation Research (CINDRR) and the use of NF/SG VA facilities for recruitment and testing
- Collaboration includes networking with CINDRR team and clinical staff of VA
- Additionally the VA provides the medical monitor for the study and VA Research Office staff review the study and oversee compliance once initiated.

Special Reporting – QUAD CHART ATTACHED as Appendix C

Appendices.

A: Products / Publications

B: CONSORT diagram

C: Quad Chart

