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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 Gainesville, FL 32610-0164

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14. ABSTRACT Veterans have an elevated crass Veterans post-deployment takes effects of TBI/ PTSD/ other blass critical information on the combineeds. Effective driving interver Furthermore, promoting driving functioning, employment, societ suggest efficacy of the OT-DI for including a small sample, attritic providing power for more details well as real world outcomes (vio	sh risk post-deployme s a multi-factorial app st related injuries as v at veterans' driving fi ntions have potential fitness may also hav al participation, and so r combat veterans w on, and mostly male s ed analyses of OT-DI olations, citations, and	ent facing un-intentiona- proach. Addressing ris vell as the impact of de tness, impact of medic to reduce driving error e carryover effects sup satisfaction with life. F ith mild TBI, PTSD, ar subjects. In our curren outcomes include red d crashes based on st	al injury or death. Our in k factors faced by veter eployment experiences, cal and psychological co s and impact real-world oporting other key arens easibility of our interver nd/or orthopedic condition t effectiveness study we duction of driving errors ate department of moto	tervention add ans necessitat exposures on onditions on dr I driving (violat as of communi- tion was teste ons. The effica e are seeking t (measured via r vehicle recor	dressing driving risks faced by tes considering co-occurring driving. Intervention provides iving, and driving rehabilitation ions, citations and crashes). ity re-integration such as family d in prior work, and early data cy study did have limitations o expand our study sample, a simulated driving evaluation), as ds).
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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 had 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

- Approved COVID mitigation plan for research resumption (VA and UF, July 2020).
- Set up new community facilities to enable research resumption in Fall 2020.
- Resumed research with 4 of 11 participants after hold lifted.
- Expanded number of community partners through outreach and community events.
- Enrolled 2 new participants during the reporting period for a total of 49 participants.
- Engaged with13 active participants (baseline testing and/or additional sessions complete with future testing pending).
- Completed all protocol sessions with 6 participants.
- Conducted outreach to VA partners across the North Florida / South Georgia VHS.
- Trained 1 undergraduate and 4 graduate research assistants.
 - Trained two driver rehabilitation specialists for driving simulator testing and intervention.
 - Trained one health sciences graduate student in implementation of traffic safety education curriculum.
- Collaborated for technology transfer of visual search strategy training to Drive Focus® application (Driver Rehabilitation Institute, 2021).
- Disseminated findings through publications listed below, with citations by additional authors across several fields of study.
- Drafted 5 manuscripts with 1 accepted for publication, 1 under revision after peer review, and 4 in development.
- Created Year 7 plan for recruitment, testing, data analyses and dissemination work.

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, traffic safety, injury prevention, social work, rehabilitation counseling, engineering, virtual reality, neurology, 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 Drive Focus, with early research demonstrating benefits of app use for enhancing driving fitness. Drive Focus was 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. However, for most of Year 6 we were under 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) which highly impacted recruitment and research resumption. At this time a Year 7 No Cost Extension is pending approval from DOD CDMRP.

Products

Publications: * indicates attached in Appendix A

- a) Publications
 - *Winter, S., Caldwell, K., Brumback, B., Jeghers, M., and Classen. S. (In press). Fidelity of a Traffic Safety Intervention. Occupational Therapy in Health Care, manuscript accepted February 2021.
- - i. Winter, S. M., **Classen, S.**, King, L. C., <u>Jeghers, M.</u>, <u>Wersal, J.</u>, <u>Medhizadah, S.</u> & <u>Yarney, A.</u> Developing an occupational therapy driving manualized intervention for returning combat Veterans. Manuscript in preparation for *OTJR: Occupation, Participation and Health.* IF=1.200
 - Classen, S., Wandenkolk, I., Yarney, A., & Winter, S. Simulated driving errors as indicators of real world driving events in returning combat veterans. Manuscript in preparation for Transportation and Health. Anticipated submission date 01 August 2021. IF=1.70*

Presentations:

- iii. *Ellison, C., Medhizadah, S., Jeghers, M., Caldwell, K., Winter, S. M., & Classen, S. Fidelity of a Traffic Safety Education intervention for combat Veterans: Lessons learned. Research poster accepted for presentation at the American Occupational Therapy Association virtual conference, April 8-11, 2021. Withdrew.
- iv. <u>*Jeghers, M., Wersal, J.,</u> Winter, S. M., & Classen, S. Rater-Reliability of assessing driving errors among returning combat Veterans. Research poster presented at the American Occupational Therapy Association virtual conference, April 8-11, 2021.

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: Co-I after March 2018 Researcher Identifier: orcid.org/0000-0002-0317-241X Nearest person month worked: 6 Contribution to Project: Dr. Winter worked with Dr. Classen on project execution, team organization and research functions. She oversaw IRB submissions, collaborated 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: Detailed below

Name: Abraham Yarney, M.E. Project Role: WOC / dissemination co-author Researcher Identifier (e.g., ORCID ID): N/A Nearest person month worked: 1 Contribution to Project: Dr. Yarney's participation this year focused on the real-world outcomes manuscript, advising on data analyses and data management. He graduated from UF with his PhD but continued support as a co-author. Funding Support: N/A

Name: Mary Jeghers, MSOT, OTR/L Project Role: Research Therapist /Graduate Research Assistant Researcher Identifier (e.g., ORCID ID): N/A Nearest person month worked: 3 Contribution to Project: Mary's primary role changed this year. Following completion of UF's Certificate Program in Driver Rehabilitation and team training, Mary assumed the Driver Rehabilitation Specialist role conducting all testing in the van and implementing the OT-DI. Secondary functions were dissemination and data management. Funding Support: Additional project funded by Florida Department of Transportation

Name: Prerna Poojary, PhD, OTR/L Project Role: Recruitment lead Nearest person month worked: 2 Contribution to Project: Apply expertise from prior clinical study recruitment and coordination, community liaison with organizations. Funding Support: N/A – balance of effort is teaching

Name: Isabelle Coppa-Wandenkolk

Project Role: Graduate research assistant

Nearest person month worked: 3

Contribution to Project: Isabelle is the primary RA for data entry and data management. Isabelle completed her VA WOC status, was added to the IRB, and trained to conduct Traffic Safety Education. She is working with Dr. Classen to analyze the data for a revision of the manuscript in development focused on real-world outcomes (violation, citation, and crash). Funding Support: Additional project is funded by VA – Office of Rural Health

Name: James Wersal, OTD, OTR/L, DRS Project Role: Research Therapist/ Graduate Student Nearest person month worked: 2 Contribution to Project: Dr. Wersal is an occupational therapist, a Driver Rehabilitation Specialist, a former Army Captain/ Army OT with combat experience. Dr. Wersal ended his graduate studies, but is a co-author on the Rater Reliability manuscript. 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 and Dr. Sandra Winter's current support for additional projects is listed below:

Current Funded Research

1. FDOT (Classen)

Total Award: \$203,947

11/21/2019-06/30/2021

Effort 15%

Project ID: BDV31 TWO 977-128

Develop, Refine and Validate a Survey to Assess Adults' Perspective of Autonomous Ride-Sharing Services.

Goal: Establish psychometrics of a survey to assess user perception of autonomous ride sharing services.

2. DOT and UF Transportation Institute (Classen)

Total Award: \$220,000 Project ID: AWD01573 03/01/2020 - 08/31/2021

06/10/2019 - 08/31/2021

Effort 10%

Effort 5 %

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 Vehicle Technology.

Goal: To build a predictive model of driver perceptions (all ages) of autonomous vehicle technology.

3. **FDOT (Elefteriadou, Classen)**

Total Award: \$134,590

Project ID: BDV31 977 115

Transportation Mobility Assessment and Recommendations for Smart City Planning **Goal:** To develop and test a community-based participatory methodology for developing transportation mobility plans by assessing the needs of travelers in the community, at two Gainesville, Florida neighborhoods: i.e., Haile Plantation and East Gainesville.

4. NIDILRR (Classen)

Total Award: \$599,99309/01/2020 - 08/30/2023Effort 10%Title: Driving Performance of People with Parkinson's using Autonomous Vehicle TechnologiesGoal: Improve the driving performance of drivers with PD via the use of in-vehicle technologies.

5. NIH (Ennis & Classen)

Total Award (UF): \$152,74109/30/2020 - 08/31/2022Effort 10%Title: Medical Marijuana Use and Driving Performance: A test of psychomotor functioning in adults 50and older

Goal: Assessing the effect of medical marijuana on response time, attention and executive functions in older adults 50 years and older.

6. North Florida/ South Georgia Region Veterans Administration (Classen)

Total Award: \$200,00007/01/2021-12/31/2022Effort 20%Title: Promoting Veteran Centric Rural Transportation Options via Automated Shuttle ExposureGoal: To quantify, qualify, and integrate rural Veterans' acceptance and adoption perceptionspertaining to automated vehicle technologies—and inform future planning and policy for ubiquitous accessible Veteran Transportation.

7. DOT and UF Transportation Institute (Classen)

Total Award: \$165,43605/15/2021- 05/31/2022Effort 9%Title: UF and UAB's Phase 2 Demonstration Study: Developing a Model to Support TransportationSystem Decisions considering the Experiences of Drivers of all Age Groups, and those withDisabilities, with Autonomous Vehicle Technology.

Goal: To build a predictive model of driver perceptions (all ages, and ability and disability levels) pertaining to autonomous vehicle technology.

8. FDOT (Classen)

services.

Total Award: \$250,00001/07/2021-12/31/2022Effort 10%Title: Florida Older Adults' Perceptions on Acceptance of Autonomous Ride Sharing Services in the
COVID-19 Era.Goal: Determine older adults' perceptions before and after exposure to autonomous ride sharing

Change of support for Dr. Winter (key personnel)

Aging Road User Information System 2020-2021 (Mason-PI)

Total Award: \$197,72510/01/20 – 09/30/21Effort 40%Florida Department of Transportation Goal: Provide database management (Florida Senior
Safety Resource Center) and audits, marketing, education, and GIS analysis of services and
gaps. Role: Project Coordinator

Child Passenger Safety Seat Fitting Station Database and Mapping 2020-2021 (Mason)

Total Award: \$90,56910/01/20 – 09/30/21Effort 20%Florida Department of Transportation Goal: Develop a database, mapping system, and
integrated website that is mobile-friendly to inform individuals about child safety seat fitting
stations across Florida's 67 counties. Role: Project Coordinator

Driving Performance of People with Parkinson's using Autonomous Vehicle Technologies (Classen)

Total Award: \$599,99309/01/2020 – 08/30/2023Effort 3%NIDILRR Project ID: 90IFRE0035 Goal: Improve the driving performance of drivers with PD via
the use of in-vehicle technologies. Role: Co-Investigator

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:

- In-kind support is provided through use via revocable license of two DriveSafety simulators
- Facilities support includes use of office space at Veterans Rural Health Resource Center (VRHRC-Gainesville) as well as the use of NF/SG VA facilities for recruitment and testing
- Collaboration includes networking with VRHRC leadership and clinical staff of VA
- Dr. David FitzGerald has been the medical monitor for the study since 2014.
- The VA Research Office staff review the study and oversee compliance with VA regulations and procedures.

Special Reporting – QUAD CHART ATTACHED as Appendix C

Appendices.

A: Products / PublicationsB: CONSORT diagramC: Quad Chart