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

PRINCIPAL INVESTIGATOR: **Sandra Winter, PhD, OTR/L**

CONTRACTING ORGANIZATION: **University of Florida
Gainesville, FL 32610**

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14. ABSTRACT This study is a follow-on to prior DOD funded work "Efficacy of a Driving Intervention Program on Safe Community Mobility for Combat Veterans". Funding for the Effectiveness (current) study was activated in October 2015. Under Aim 1, Major Task 1 is to "Prepare Regulatory Documents and Research Protocol" - University of Florida (UF), North Florida/South Georgia Veterans Affairs, and DOD HRPO approvals were achieved in the last half of 2016. The research team at UF has doubled since start of 2017, with Dr. Classen now at UF and the addition of 3 Research Assistants. Our research therapist has a start date of June 1 st with training scheduled on the simulator to ensure intervention fidelity. We are in position to enroll subjects in July and have reached out to our network of 40 plus VA and community contacts. Additional work under Specific Aim 1 to enhance the OT-DI with development of targeted simulator drives addressing CV driving triggers and assess user satisfaction is progressing. To enhance the rigor of the testing we are ensuring that the simulator drives have an appropriate randomization of events to prevent learning effect. A drive is ready with a boxed-in scenario which we will be able to test with initial subjects to obtain user feedback.					
15. SUBJECT TERMS Randomized Clinical Trial, Intervention, Driving, Rehabilitation, Simulation					
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Table of Contents

1. Introduction.....	1
2. Keywords.....	1
3. Accomplishments.....	1
4. Impact.....	2
5. Changes/problems.....	2
6. Products.....	2
7. Participants and other collaborating organizations.....	4
8. Special reporting requirements.....	6
9. Appendices (list).....	7

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. Our pilot study data suggest efficacy of the OT-DI for combat veterans with mild TBI, PTSD, and/or orthopedic conditions but limitations include a small sample, attrition, and mostly male subjects. Further study will enable more detailed analysis of OT-DI outcomes include reduction of driving errors (measured via simulated driving evaluation), as well as real world outcomes including decreased difficulty in driving based on caregiver report and a reduction in violations, citations, and crashes based on state department of motor vehicle records. Our next step is to expand study of the OT-DI to a larger population in order to obtain further support for both its efficacy and effectiveness.

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

Accomplishments

Working with UF Vice-president for Research we activated funding for the Effectiveness study in October 2015. Study kick-off was held December 2015. Currently the team meets twice a week, with daily team training for new hires on processes for screening, enrollment, data collection, VA research processes (e.g., transportation and storage of data for confidentiality and security), clinical and simulator assessment.

Under Aim 1, Major Task 1 is to "Prepare Regulatory Documents and Research Protocol" - University of Florida (UF), North Florida/South Georgia Veterans Affairs, and DOD HRPO approvals were achieved in the last half of 2016. The research team at UF has doubled since start of 2017, with Dr. Classen now at UF and the addition of 3 Research Assistants. Our research therapist has a start date of June 1st with training scheduled on the simulator to ensure intervention fidelity. We are in position to enroll subjects in July and have reached out to our network of 40 plus VA and community contacts.

Under Specific Aim 1 to enhance the OT-DI with development of targeted simulator drives addressing CV driving triggers and assess user satisfaction - we worked with simulator drive developer DriveSafety to enhance the rigor of the testing. We are ensuring that the simulator drives have an appropriate randomization of events to prevent learning effect. A drive is ready with a boxed-in scenario which we will be able to test with initial subjects to obtain user feedback.

Over this grant cycle we completed an interim analysis of the efficacy data and published these findings in early 2017 (see publications below and also appendix).

This study provides opportunities for joint UF-VA training of faculty, staff, and student trainees. Staff or trainees not employed by VA and who will be engaged at VA facilities or with participants will train as WOC (Without compensation) and obtain study-required VA privileges. Professional development via manuscripts and presentations is described under products.

Key dates: March 2016 – Submission sent for VA review and approval; June 2016 – VA approval to submit to UF IRB-01; September 2016 – UF IRB-01 approval; December 2016 – DOD HRPO approval; January 2017 – Dr. Classen starts position as Chair of Dept. of Occupational Therapy at UF; March to April 2017 – Hiring of Dr. Luther King, OTR/L, DRS with June 1 start date.

Impact

Impact on principal and related disciplines: Dissemination of findings is critical for rehabilitation fields such as occupational therapy and driving rehabilitation. We have continued with dissemination activities based on findings from the initial award “Efficacy of a Driving Intervention Program on Safe Community Mobility for Combat Veterans”. Currently simulators are at use across both military medicine and VA health care settings, but without evidence for effectiveness of a manualized simulator intervention for driving rehabilitation. Studies on this topic are limited (fewer than five known to this author). Our impact activities include presentations and manuscripts and are listed under products heading below.

Impact on technology transfer: Content for veteran-centric driving rehabilitation being developed for these drives will become part of package for simulators sold to military and veteran health settings. Details of the driving scenarios are also described in detail in dissemination materials so concepts can be adapted for other forms of technology (i.e. other simulators or educational content).

Impact on society: Beyond direct intervention to veterans, we engage in activities to raise awareness of driving safety in the larger population and the need to ensure appropriate and safe options for community mobility and integration of all citizens.

Changes/problems

Dr. Winter continues to have a need for recurrent medical leave, with anticipated extended leave in the next grant cycle. For this reason, and to ensure progress and achievement of grant goals, Dr. Classen will replace Dr. Winter as study PI following her VA clearance and credentialing. Additionally, expenditures to date are less due to delayed initiation (explained above) and hiring of Research Therapist with associated training occurring in year two vs. year one.

Products

A simulator drive (tailored content for a veteran-centric intervention) is under development by DriveSafety (simulator manufacturer).

In addition we have continued dissemination activities based on initial DOD study findings.
Publications:

Classen, S., Winter, S.M., Monahan, M., Lutz, A., Platek, K., & Yarney, A. (2017). Driving intervention for returning combat veterans: Interim analysis of a randomized controlled trial. *OTJR: Occupation, Participation and Health*, 37(2), 62-71.doi:10.1177/1539449216675582

Winter, S. M., Sursky, S., Classen, S, Yarney, A., Monahan, M., Platek, K., Lutz, A. L., Levy, C. (2016). Intermediate term effects of an occupational therapy driving intervention for combat veterans. *American Journal of Occupational Therapy*, 70(4_Supplement_1):7011515253p1.

Products (continued)

- Winter, S. M., Szafranski, E., Classen, S., Yarney, A., Monahan, M., Platek, K., Lutz, A. L., Levy, C. (2016). Combat veterans' strategies to manage risky driving and preferences for driving intervention. *American Journal of Occupational Therapy*, 70(4_Supplement_1):7011515253p1.
- Classen, S., Yarney, A. K. A., Monahan, M., Winter, S. M., Platek, K., & Lutz, A. L. (2015). Rater reliability to assess driving errors in a driving simulator. *Advances in Transportation Studies, an International Journal*.
- McGowan C. (2014). Combat Veterans' Perspectives on Driving Strategies to Curtail Unsafe Driving. (Honor thesis).
- Szafranski, E. (2015). Understanding Combat Veterans Perspectives on Strategies to Manage Unsafe Driving and Preferences for Driving Intervention. (Honor thesis).
- Sursky, S. (2015). Intermediate Term Effects of an Occupational Therapy Driving Intervention for Combat Veterans. (Honor thesis).
- Miller, K. (2015) Combat Veteran Community Integration in a Driving Intervention. (Honor thesis).

Presentations:

- Classen, S., Winter, S. M., Levy, C., Yarney, A., & Monahan, M. Driving intervention for returning combat veterans: Interim analysis of a randomized controlled trial. Poster presented at the American Occupational Therapy Association's 2017 Annual Conference, March 30 – April 2, 2017, Chicago, Illinois.
- Winter, S. M., Szafranski, E., Classen, S., McGowan, C., Levy, C., Monahan, M., & Yarney, A. Grounded theory focus group findings in combat veteran with driving performance issues. Poster presented at the American Occupational Therapy Association's 2017 Annual Conference, March 30 – April 2, 2017, Chicago, Illinois.
- Winter, S. M., McCarthy, D., Pomidor, A., & Holley, G. Florida Department of Transportation Health Care Needs Assessment. Short Course Presented at the Florida Occupational Therapy Association Annual Conference, Orlando, November 4-5, 2016.
- Szafranski, E., Winter, S. M., Classen, S., Yarney, A., & Levy, C. Combat veterans' strategies to manage risky driving and preferences for driving intervention. Poster presented at the American Occupational Therapy Association's 2016 Annual Conference, April 7, Chicago, Illinois.
- Sursky, S., Winter, S. M., Classen, S., Yarney, A., Monahan, M., Lutz, A., Platek, K., & Levy, C. Efficacy of a simulator-based occupational therapy driving intervention for returning combat veterans. Poster presented at the American Occupational Therapy Association's 2016 Annual Conference, April 7, Chicago, Illinois.
- Szafranski, E., Winter, S. M., Classen, S., Yarney, A., & Levy, C. Combat veterans' strategies to manage risky driving and preferences for driving intervention. Poster presented at the Florida Occupational Therapy Association's 2015 Fall Conference, Nov 6-7, Kissimmee, Florida.
- Sursky, S., Winter, S. M., Classen, S., Yarney, A., Monahan, M., Lutz, A., Platek, K., & Levy, C. Efficacy of a simulator-based occupational therapy driving intervention for returning combat veterans. Poster presented at the Florida Occupational Therapy Association's 2015 Fall Conference, Nov 6-7, Kissimmee, Florida.

Products continued

Winter, S. M., Special populations/conditions: Returning combat veterans. Presented at the 39th Association for Driving Rehabilitation Specialists (ADED) Annual Conference. Louisville, Kentucky, August 1, 2015, as part of the symposium "Driving Simulation: Sharing evidence, enhancing practice" (Classen, S. – lead author/ moderator).

Szafranski, E., Winter, S. M., Classen, S., & Levy, C. Combat veterans' strategies to manage risky driving and preferences for driving intervention. Poster presented at the 39th annual Association for Driving Rehabilitation Specialists (ADED) Annual Conference. Louisville, Kentucky, August 1, 2015

Sursky, S., Winter, S. M., Classen, S., Yarney, A., Monahan, M., Lutz, A., Platek, K., & Levy, C. Intermediate-term effects of an occupational therapy driving intervention for combat veterans. Poster presented at the 39th annual Association for Driving Rehabilitation Specialists (ADED) Annual Conference. Louisville, Kentucky, August 2, 2015.

Winter, S. M., Classen, S., Levy, C., Yarney, A., Monahan, M. Sursky, S., and Szafranski, E. Efficacy of a driving intervention for Veterans with polytrauma using a simulator. Poster presented at the VA RR&D Polytrauma conference "New Perspectives in TBI Rehabilitation". Hyattsville, Maryland, May 5-6, 2015.

Cormack, N., Classen, S., Monahan, M., Winter, S.M., Yarney, A., Lutz, A., Platek, K., & Levy, C. Efficacy of an occupational therapy driving intervention for OEF/OIF combat Veterans: A pilot study. Poster presented at the 95th American Occupational Therapy Association Annual Conference. Nashville, Tennessee, April 18, 2015.

Participants and other collaborating organizations

Veterans Affairs is a collaborator on this study with involvement of both the Center of Innovation on Disability and Rehabilitation Research, a VA Center of Innovation, and the North Florida/ South Georgia Veterans Health System. 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. One Co-I, Dr. Sherrilene Classen, is at the University of Western Ontario, London, Ontario, Canada.

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

Name: Sandra Winter, PhD, OTR/L

Project Role: PI

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

Nearest person month worked: 5

Contribution to Project: Dr. Winter will have overall responsibility for the project execution. She will organize the research team and oversee all the 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 will supervise the research coordinator, research therapist and research assistants, oversee data collection, analysis and interpretation, and develop manuscripts, research presentations and reports.

Funding Support: N/A

Participants and other collaborating organizations (continued)

-5-

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

Project Role: Co-I

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

Nearest person month worked: 3

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

Funding Support: N/A

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 whose salary is paid by VA, his effort is listed as 5%.

Name: Michael Marsiske, PhD

Project Role: Co-I

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

Nearest person month worked: 1

Contribution to Project: Dr. Marsiske will collaborate with the team and the biostatistician on data analyses to look at the contribution of the evaluation battery to predicting real world driving performance. He will assist in development of study design, recruitment, and outcomes dissemination.

Funding Support: N/A

Name: Abraham Yarney , M.E.

Project Role: Graduate Student

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

Nearest person month worked: 4

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 data analysis overseen by the team and the biostatistician.

Funding Support: N/A

Name: Katelyn Caldwell, BHS student

Project Role: Honors Student / Research Assistant

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

Nearest person month worked: 4

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

Name: Mary Jeghers, MSOT, OTR/L

Project Role: Graduate Student

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

Nearest person month worked: 4

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: N/A

Name: Shabnam Medhizadah, MS

Project Role: Graduate Student

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

Nearest person month worked: 4

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: 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? Dr. Classen's employment changed from University of Western Ontario to University of Florida as of January 2017 as further explained below.

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.

2) Organization Name: University of Western Ontario (UWO)

Location of Organization: London, Ontario, Canada

Partner's contribution to the project: Dr. Classen is a Co-I / Consultant and scientific advisor to the UF team, based in part on her role as PI of the original DOD intervention study. * NOTE – Dr. Classen moved from UWO to UF as Chair of Dept. of Occupational Therapy on January 2, 2017.

Special reporting requirements

Updated Quad Chart is attached

Appendices (Key Documents, Publications and Presentations from 4-16-2016 to 4-15-2017)

Appendix A: Quad Chart

Appendix B: University of Florida IRB-01 approval letter

Appendix C: Publications –

Manuscript

Classen, S., Winter, S.M., Monahan, M., Lutz, A., Platek, K., & Yarney, A. (2017). Driving intervention for returning combat veterans: Interim analysis of a randomized controlled trial. *OTJR: Occupation, Participation and Health*, 37(2), 62-71. DOI:10.1177/1539449216675582

Abstracts (Posters attached from presentations – Abstracts on-line only at DOI listed)

Winter, S. M., Sursky, S., Classen, S, Yarney, A., Monahan, M., Platek, K., Lutz, A. L., Levy, C. (2016). Intermediate term effects of an occupational therapy driving intervention for combat veterans. *American Journal of Occupational Therapy*, 70(4_Supplement_1):7011515253p1. DOI: 10.5014/ajot.2016.70S1-PO1063

Winter, S. M., Szafranski. E., Classen, S, Yarney, A., Monahan, M., Platek, K., Lutz, A. L., Levy, C. (2016). Combat veterans' strategies to manage risky driving and preferences for driving intervention. *American Journal of Occupational Therapy*, 70(4_Supplement_1):7011515253p1. DOI: 10.5014/ajot.2016.70S1-PO2024

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



Award Number – W81XWH-15-1-0032

PI: Winter, Sandra Mae Org: University of Florida

Award Amount: \$1,781,608

Study/Product Aim(s)

Specific Aim 1. Enhance the OT-DI with development of targeted simulator drives addressing CV driving triggers and assess user satisfaction (n=30)

Specific Aim 2. Evaluate group differences among the OT-DI group and the traffic safety education group measuring at baseline, post-intervention and three months post-intervention: (a) the type and number of driving errors made on a simulator, (b) CV and caregiver rating of driver difficulty, and (c) archival records, i.e. state-recorded violations, citations, and crashes. (n=180 Veterans and 150 Caregivers)

Specific Aim 3. Determine effectiveness of the OT-DI, specifically addressing the impact of the OT-DI vs. traffic safety education in reduction of total driving errors and critical driving errors such as speeding measured during simulated driving.

Specific Aim 4. Examine the impact of the OT-DI and traffic safety education on real-world driving in a sub-set of CVs (n=30) using on-road testing.

Approach: Effectiveness study of a clinical intervention using a repeated measures design.



Accomplishment: Study received VA, Univ. Florida IRB, and HRPO approval during this period. Simulator drive development will be ready for testing with subjects in August 2017. Study team has increased with key appointments and preparing to recruit.

Timeline and Cost

Activities	CY	14	15	16	17
Aim 1. Refine intervention					
Aim 2. Evaluate group differences					
Aim 3. Examine tx effect simulator					
Aim 4. Examine tx effect real-world driving					
Estimated Budget (\$K)		\$518	\$450	\$462	\$415

Goals/Milestones

CY14 Goal – Refine intervention

- ☐ Complete user evaluation of simulator drives and integrate into intervention

CY15 Goals – Evaluate group differences

- ☐ Compare type and number of errors made on simulator
- ☐ Analyze CV and caregiver rating of driver difficulty (pre/post)

CY16 Goal – Examine treatment effect in simulator

- ☐ Determine effectiveness of the OT-DI, specifically addressing the impact of the OT-DI vs. traffic safety education

CY17 Goal – Examine treatment effect on real-world driving

- ☐ Analyze archival records, i.e. state-recorded violations, citations, and crashes

Comments/Challenges/Issues/Concerns

- We expect retention of subjects to be our biggest challenge and have a multi-faceted plan to reduce attrition across sessions

Budget Expenditure to Date : \$165,965 as of 6/15/2017

Updated: 5/15/2017

Driving Intervention for Returning Combat Veterans: Interim Analysis of a Randomized Controlled Trial

OTJR: Occupation, Participation and Health
1–10
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DOI: 10.1177/1539449216675582
otj.sagepub.com


Sherrilene Classen¹, Sandra Winter^{1,2}, Miriam Monahan³,
Abraham Yarney¹, Amanda Link Lutz⁴, Kyle Platek⁴, and Charles Levy²

Abstract

Increased crash incidence following deployment and veterans' reports of driving difficulty spurred traffic safety research for this population. We conducted an interim analysis on the efficacy of a simulator-based occupational therapy driving intervention (OT-DI) compared with traffic safety education (TSE) in a randomized controlled trial. During baseline and post-testing, OT-Driver Rehabilitation Specialists and one OT-Certified Driver Rehabilitation Specialist measured driving performance errors on a DriveSafety CDS-250 high-fidelity simulator. The intervention group ($n = 13$) received three OT-DI sessions addressing driving errors and visual-search retraining. The control group ($n = 13$) received three TSE sessions addressing personal factors and defensive driving. Based on Wilcoxon rank-sum analysis, the OT-DI group's errors were significantly reduced when comparing baseline with Post-Test 1 ($p < .0001$) and comparing the OT-DI group with the TSE group at Post-Test 1 ($p = .01$). These findings provide support for the efficacy of the OT-DI and set the stage for a future effectiveness study.

Keywords

veterans, simulation, driving, efficacy trial

Background

Motor vehicle crashes (MVCs) are one of the leading causes of death, injury, and hospitalization of returning combat veterans (CVs) from Operation Iraqi Freedom and Operation Enduring Freedom (OIF/OEF; Lew et al., 2011; Woodall, Jacobson, & Crum-Cianflone, 2014). MVCs are responsible for one third of all deaths of post-deployed CVs (Woodall et al., 2014). Increased MVCs have been associated with battlemind driving (defensive and offensive driving behaviors necessary for survival during combat) and diagnosis of polytrauma, traumatic brain injury (TBI), and/or post-traumatic stress disorder (PTSD; Cifu et al., 2013; Classen, Cormack, et al., 2014; Classen et al., 2011; Lew, Amick, Kraft, Stein, & Cifu, 2010). Efficacy studies testing interventions on veterans to reduce driving errors, the purpose of this study, are limited, yet critically needed (Classen et al., 2011).

prevails during civilian driving (Hoggatt et al., 2015; Lew et al., 2010). Aggressive driving tactics ingrained during combat training such as speeding, driving in the center of the road, and refusing to yield right-of-way and quick lane changes can be dangerous to the drivers, passengers, and pedestrians during civilian driving (Lew et al., 2010). CVs with multiple deployments are at even greater risk of crash involvement (Woodall et al., 2014). This may be due to battlemind driving habits, as well as the lack of mitigation strategies to combat such driving behaviors (Woodall et al., 2014). However, aside from potential causes such as being male, young, and having an “alpha male” role to fulfill during combat (Hannold, Classen, Winter, Lanford, & Levy, 2014, p. 1324), other documented causes (next discussed) include effects of polytrauma following blast

Literature Review

Battlemind Driving

Regardless of diagnoses, most CVs are at risk of impaired driving and crashes due to battlemind driving, that is, the defensive and offensive driving behaviors necessary for survival during combat, and although not necessary, still

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injuries (e.g., residual symptoms of a mild TBI or PTSD; Classen, Cormack, et al., 2014).

Polytrauma

Explosive injuries such as those caused by car bombs and improvised explosive devices (IEDs) are the most common causes of injury to CVs engaged in OIF/OEF conflicts (Cifu et al., 2013). Polytrauma, a condition predominately associated with OIF/OEF conflicts, is defined as “two or more injuries, one of which may be life threatening, sustained in the same incident that affect multiple body parts or organ systems and result in physical, cognitive, psychological, or psychosocial impairments and functional disabilities” (Department of Veterans Affairs, 2013, VHA Handbook 1172.0, p. 1) such as co-occurring TBI, PTSD, and musculoskeletal injury. Cifu and colleagues (2013) examined the records of all OIF/OEF and Operation New Dawn (OND) veterans from 2009 to 2011, and identified that 62.5% of the CVs with TBI also met the criteria for polytrauma. As such, polytrauma occurs in a significant cohort of the CVs.

TBI

TBI is caused by an external force affecting the head and results in alterations in brain function that can be long term or transient. Mild TBI, the signature injury of veterans from OIF/OEF, is defined as loss of/altered consciousness of less than 30 min and a Glasgow Coma Scale of 13 to 15 (Centers for Disease Control and Prevention [CDC], the National Institutes of Health [NIH], the Department of Defense [DoD], & the Department of Veterans Affairs [VA] Leadership Panel, 2013). From 2000 to 2015, CVs have experienced more than 340,000 TBIs with the majority classified as mild TBIs (Defense and Veterans Brain Injury Center, 2016). TBI is a common combat-related injury and may have a negative impact on driving performance, including errors in speed regulation and/or difficulty with adjustment to stimuli (appropriate reaction to trigger stimulus; Classen et al., 2011).

PTSD

PTSD can occur after an individual experiences a terrifying event (National Institute of Mental Health [NIMH], 2016). Symptoms of PTSD include reliving traumatic experience(s) through flashbacks and dreams, avoidance and hyperarousal (NIMH, 2016). From 2000 through mid 2015, 138,971 returning CVs from OIF/OEF had a diagnosis of PTSD (Fischer, 2015). Driving can trigger CVs to experience flashbacks and react as if they were in the battlefield (Lew et al., 2010). CVs with PTSD are more likely to experience driving anxiety, particularly when civilian driving situations imitate dangerous battlefield situations, such as being tailgated (Zinzow, Brooks, & Stern, 2013). Hannold et al. (2014) reported that CVs with mild TBI and PTSD experienced a

range of emotional responses triggered by different driving situations. For example, traffic jams triggered an anxiety response; overpasses and intersections triggered a speeding response; and being cut-off from a roadway triggered an anger response. The combination of mild TBI and PTSD may further have a negative impact on the CVs' driving performance (Lew et al., 2010).

The need is to safely and accurately assess driving performance issues among these CVs and to provide them with intervention strategies that can curb battlemind driving behaviors, and the residual effects of polytrauma, mild TBI, and/or PTSD.

Driving Assessment and Intervention

Driving simulators, widely used to assess driving performance, are safe alternatives to the on-road assessment that may pose risks related to real-world circumstances, environments, and traffic conditions (Amick, Kraft, & McGlinchey, 2013; Classen, Cormack, et al., 2014; Classen et al., 2011). For example, Classen et al. (2011) conducted a study with 18 CVs from OIF/OEF with mild TBI and PTSD. These CVs made significantly more speeding and adjustment-to-stimuli errors and total number of driving errors than healthy controls. In follow-up driving simulator studies, researchers examined the benefit of an occupational therapy driving intervention (OT-DI) in reducing driving errors for a single subject (Classen, Monahan, Canonizado, & Winter, 2014), and among eight CVs diagnosed with orthopedic injury, mild TBI, PTSD, and/or polytrauma (Classen, Cormack, et al., 2014). These participants completed baseline testing (clinical tests of vision, cognition, and motor abilities, followed by a simulated drive) where seven driving errors were assessed, followed by three OT-DI sessions and a post-test (using the same procedure as baseline testing). The intervention utilized coaching strategies facilitated by the occupational therapist driving rehabilitation specialist (OT-DRS) to raise the CVs' self-awareness of driving errors (Session 1), visual-search skills training to detect critical roadway information (Session 2), and strategy implementation while driving with verbal commentary during the drive (Session 3). In the single-subject study, the overall driving errors were reduced post-intervention from 33 to 9 (Classen, Monahan, et al., 2014). The post-intervention results of the second study demonstrated a reduction ($p < .05$) in lane maintenance errors, as well as total number of driving errors (Classen, Cormack, et al., 2014). These two studies, although limited by small sample sizes and lack of control groups, suggest that a simulator-based OT-DI can provide a safe environment for testing and training of CV to reduce dangerous driving errors.

Purpose

The purpose of this study was to determine if an OT-DI (three 1-hr sessions as previously described) significantly

reduces the driving errors (type and number) in CV compared with a traffic safety education (TSE) in a randomized controlled trial. The finding of this research is critical for validating the efficacy of an OT-DI. If the OT-DI proves to be valid, this intervention could prevent needless driving-related injuries and deaths in CVs and others affected by reckless driving.

Method

This study was approved by the University of Florida's (UF) Institutional Review Board, the North Florida/South Georgia Veterans Affairs (VA) Research Committee, University of Western Ontario's Research Ethics Board as an exempt application, and the Department of Defense Human Research Protection Office (HRPO). This trial is registered with the ClinicalTrials.gov U.S registry (NCT02764983), <https://clinicaltrials.gov/ct2/show/NCT02764983>. All participants were informed of study risk and benefits through a verbal and written informed consent process. Privacy of all participants was maintained according to UF and Veterans Affairs (VA) procedures requiring their identity not be disclosed.

Design

We employed an unblinded parallel arm randomized controlled design with random allocation of participants to an intervention and control group.

Participants

Recruitment. CVs were recruited through in-person visits or flyers distributed in VA settings (Physical Medicine and Rehabilitation Clinic, OEF/OIF & Seamless Transition Program, Women's Clinic, and Community-Based Out-Patient Clinics). Likewise, recruitment was extended to veteran-centric community locations such as the Vet Centers, Veteran Student Groups, and the Wounded Warriors' TRACK Program in Jacksonville, Florida.

Sample size. We completed an interim (prior to completion of the study) analysis on 26 of the 60 participants. The final analysis has been powered ($\alpha = .05$, $\beta = 20\%$, effect size = .40) to determine if significant differences exist in the main dependent variable, that is, *number of driving errors*.

Random allocation. Based on the CONSORT 2010 Statement (Schulz, Altman, & Moher, 2010), we used a flow diagram to track and report our enrollment and group allocation (flow diagram not shown). We used a computer-generated block ($\times 6$) randomization scheme to assign participants to either an intervention or control group. At the time of this analysis, 26 participants (13 per group) who had completed study sessions through Post-Test 1

were included. The preliminary analysis was conducted to report progress on the actual study.

Inclusion criteria. CVs who have polytrauma (mild TBI/PTSD, traumatic limb amputation/fractures); drove prior to their injury/condition; have a valid driver's license; are community dwelling; have potential for following driving safety recommendations; scored no less than 24/30 on the Mini-Mental State Examination (MMSE); have the potential for following community integration strategies (MMSE 24/30); and who are able to participate in a driving evaluation as per self-assessment were included.

Exclusion criteria. CVs who have severe psychiatric (e.g., psychoses) or physical conditions (e.g., missing both arms and/or legs) that limit their ability to drive; have multiple psychotropic medications that may affect mental or physical (due to side-effects) functioning as per the consulting physician; have severe, irremediable medical conditions (e.g., severe TBI) as per the consulting physician; are pregnant females or those planning pregnancy as determined per self-report; and VA employees were excluded.

Procedure

After the participants provided informed consent, the team followed standardized protocols (Classen, Cormack, et al., 2014; Classen et al., 2011) to pursue with baseline testing. This included obtaining intake information, administering a clinical battery of visual (and other sensory), cognitive, and motor tests, and performing a standardized simulated driving assessment described below (Classen, Cormack, et al., 2014; Classen et al., 2011; Classen et al., 2015).

Driving simulator. The DriveSafety CDS-250 (Figure 1; DriveSafety, 2014) has a Ford Focus console configuration. The simulator's control devices include a steering wheel with active force feedback, automatic transmission, turn signals, and gas and brake pedals. The simulator's displays include a speedometer and a high-fidelity audio sound simulation of engine sounds. It has a 65° field of view with rendered scenes representing 110° horizontal view on tri-screen monitors, with side and rear view mirrors. The CDS-250 is equipped with record and playback functionality. The simulator is engineered in the back of the Dodge Sprinter van (Figure 2) and is used as a mobile simulator, meaning that the study team can access participants with transportation problems, or those who live in remote areas.

Acclimation scenario. All drivers were introduced into the simulator through an acclimatization process of three short (2-3 min) driving segments focused on operation of simulator controls, lane keeping, speed maintenance, and stopping. The acclimation process allowed CVs to physiologically adjust to the simulator.



Figure 1. Dodge sprinter van with the CDS-250 simulator engineered into the cab of the van.



Figure 2. DriveSafety CDS-250 high-fidelity driving simulator.

Driving scenario description

Residential and suburban drive scenario (6 min). This drive starts in a residential neighborhood on a narrow two-lane road with no markings and a 25-mph speed limit. This road section shows traffic, parked cars, trash cans at the curb, pedestrians, and features such as roadkill. The driver encounters four-way stop intersections, transitions to a rural two-lane road at 45 mph, and then to a commercial four-lane road at 35 mph with busy intersections. Three challenges occur requiring vigilance from the driver to avoid possible adverse events: (a) a pedestrian entering the crosswalk of the street that the driver is turning onto, (b) an unprotected left turn at an intersection with oncoming traffic in opposing lanes, and (c) sudden braking of a lead vehicle.

City and highway scenario (10 min). This drive starts in an urban area presenting multi-lane (4+) and narrow city streets, moderate traffic, and pedestrians. The drive proceeds to freeway driving with features such as roadside debris, a

disabled vehicle, and a tow truck. Three challenges occur; each requiring the vigilance of the driver to avoid possible adverse events. These are as follows: (a) a parked car pulling out in front of the driver, (b) the driver making an unprotected left turn, and (c) a pedestrian stepping from behind a parked car into the path of the driver.

Simulator Sickness Questionnaire (SSQ). Based on previous findings, we expected minimal occurrence of simulator sickness (SS; Classen, Cormack, et al., 2014). Still, every participant completed the SSQ before and after the acclimation and main drives (Kennedy, Lane, Berbaum, & Lilienthal, 1993). Following the standard protocol, we optimized the environment for mitigating or preventing symptoms of SS (Classen & Owens, 2010). Individual participants who showed an increase from baseline SS scores were offered rest breaks and were kept comfortable before they were dismissed from the intervention. Overall, the SS data are not further discussed because we had no significant findings within or between groups for SSQ scores.

We examined participants' demographics using standardized data collection sheets (Classen, Cormack, et al., 2014; Classen et al., 2011). The evaluators, one OT-CDRS and two OT-DRSs, administered the assessment and provided the driving intervention. Reliability among the three evaluators was established with 99.3% agreement among raters for the city/highway and 98% agreement for the residential/suburban conditions (Classen et al., 2015). The evaluators administered the visual, sensory, cognitive, and motor assessments. Consistent with the general driving literature, the MMSE that was used as a screening test of gross cognitive ability and CVs who scored less than 24 were excluded from participation (Crizzle, Classen, Bédard, Lanford, & Winter, 2012; Fox, Bowden, & Smith, 1998; Marottoli et al., 1998; Odenheimer et al., 1994; Trobe, Waller, Cook-Flannagan, Teshima, & Bieliauskas, 1996). Valid and/or reliable clinical tests included the Useful Field of View™ (UFOV), a visuo-cognitive test (Owsley et al., 1998); comprehensive vision tests, including visual acuity, peripheral vision, contrast sensitivity, stereopsis, depth perception, and lateral/vertical phorias, assessed with Optec 2500 (Stereo Optical Company Inc, 2009); and motor tests, including the finger-to-nose (Walker, 1990) and toe-tap tests (Molnar et al., 2007).

The evaluators assessed seven driving errors (type and number) with a standardized score sheet (Classen et al., 2011), while participants drove the simulator. These errors included speed regulation (maintaining the speed limit $\pm$ 5mph), lane maintenance (lateral position of the vehicle), visual scanning (during lane changes and at intersections), gap acceptance (determining safe timing for crossing in front of oncoming traffic), adjustment-to-stimuli (responding to road signs, pedestrians, or hazards), vehicle positioning (adequate space behind lead vehicle and stop line), signaling (correct use of turn signals), and total number of driving errors (sum of all the previous errors).

After baseline testing, the participants were randomly assigned to the balanced OT-DI (10 CVs with TBI/PTSD and three CVs with orthopedic conditions) and TSE group (seven with TBI/PTSD and six with orthopedic conditions). *Equipoise* (equality among two treatment arms and outcomes not known to the researcher), *concealed assignment* (group designation only disclosed at the end of study to the participants), and *intent to treat analyses* (concerted effort to mitigate attrition) were maintained.

Intervention group. The intervention group received the OT-DI consisting of three 1-hr sessions delivered by the evaluators. As discussed, Session 1 included the evaluator reviewing explicit driving errors with the CVs and suggesting tailored strategies to mitigate errors. For example, as the CV experienced hypervigilance in a stressful situation, such as encountering a dead animal in the simulated road scene, and performed a corresponding driving behavior, for example, speeding or wide swerving (to avoid the stimulus), the evaluator identified such behaviors and aberrant driving errors, discussed those with the CVs, and identified strategies to overcome these behaviors. In Session 2, the evaluators provided a visual-search training session to enhance the CV's ability to identify and react appropriately to critical roadway information (e.g., identifying brake lights and slowing down), while suppressing inappropriate or less critical roadway information (e.g., looking at billboards or brush, where snipers would hide in the battlefield, and as such not paying attention to the critical roadside information; Monahan, 2009). During Session 3, the CV drove the simulator, while incorporating the strategies from the previous two sessions and narrating the drive to provide an audible account of implementing the strategies. After the drive, each CV received targeted feedback from the OT-DRS.

Control group. The control group received 3 hr of TSE based on a Safety Council curriculum delivered initially by a traffic safety official and eventually via video. The traffic safety official (and video recordings) used a manualized curriculum with handbook for the Basic Driver Improvement course (National Traffic Safety Institute, 2011). These three 1-hr discussions focused on sharing traffic knowledge, vehicle safety, crash prevention, driving risk control/defensive driving, psychological factors, and driving under the influence of alcohol and substances.

Post-Test 1. Although the OT-DI group underwent Post-Test 1 immediately following Session 3, the TSE group had a time variation for participating in this session ($M = 16.5$ days, $SD = 17.72$ days). Post-Test 1 used the same standardized protocol outlined as for baseline testing. All CVs were reimbursed \$25 USD for the 1-hr training sessions but \$50.00 USD for the 3-hr baseline and post-test sessions.

Data Collection and Management

Data were collected by the evaluators, and a trained research assistant entered the data. These data were stored in a password-protected and secure server consistent with the security, privacy, and confidentiality policies of the participating university and the VA. All hard copies were stored in a fire-proof-locked filing cabinet in a locked research office at the VA. The study principal investigator performed regular data checks to identify and correct, with the research assistant, missing data or data entry errors. Data were typically entered within 2 to 3 days after the assessment or intervention session, and any discrepancies were resolved with the evaluator collecting the data.

Data Analysis

We used descriptive statistics to summarize nominal, ordinal, and numerical data. For between-group differences and after confirming uneven distribution (expected due to small sample sizes) with a Shapiro–Wilk test, the non-parametric Wilcoxon rank-sum test (between-group differences) was used to report on the difference in type and number of driving errors at baseline and Post-Test 1 for the OT-DI and TSE groups. For detecting between-/within-group differences with nominal/ordinal data, we used Fisher's exact test or the chi-square test, and a paired sample t test for determining the driving error difference scores of the means for baseline and Post-Test 1 for each group. We used IBM SPSS statistics Version 22 (IBM Corporation) for the analyses. Significance testing was conducted at $p \leq .05$, two tailed.

Results

The demographics characteristics for CVs ($N = 26$) by intervention ($n = 13$) and control groups ($n = 13$) demonstrated that CVs were all male, mostly White, with the majority having education past high school and being married. The mean age of participants was 38.69 ± 6.52 for the intervention group, and the mean age was 37.31 ± 10.21 for the control group. Most (>60%) of the CVs in each group did not report a crash in the last 3 years; however, self-reported citation rates in the last 3 years varied from 30% for the intervention group to 58% for the control group. We found no differences between any of the other variables in the between-group analysis. Moreover, the intervention group had exclusively White participants, while the controls had White (61.5%) and other (38.5%) racial categories. Based on the demographic variables, the findings suggest that the groups were not statistically significantly different.

No statistical differences existed for exposures between the two groups. However, the data suggested that the most common exposures (of injury) for both groups were mortars (61% for both groups), IEDs (61.5% for the intervention group; 38.5% for the control group), motor vehicle accidents

Table 1. Mean and Standard Deviation for Driving Errors at Baseline and Post-Test 1 for Combat Veterans ($N = 26$) by Intervention ($n = 13$) and Control ($n = 13$) Groups.

Driving error type	Intervention group		Control group	
	Baseline	Post-Test 1	Baseline	Post-Test 1
	<i>M</i> (<i>SD</i>)	<i>M</i> (<i>SD</i>)	<i>M</i> (<i>SD</i>)	<i>M</i> (<i>SD</i>)
Speeding	12.31 (7.40)	4.92 (4.09)	13.00 (7.81)	10.08 (7.30)
Underspeeding	7.08 (6.10)	3.00 (3.67)	7.31 (8.56)	4.38 (4.92)
Overspeeding	5.23 (7.05)	1.92 (2.25)	5.69 (7.47)	5.69 (7.76)
Lane maintenance	12.23 (5.78)	6.15 (4.51)	9.92 (5.57)	8.69 (5.21)
Vehicle positioning	2.38 (1.89)	0.62 (0.65)	1.85 (1.68)	1.15 (1.14)
Gap acceptance	2.08 (1.04)	1.23 (1.30)	2.07 (1.32)	2.46 (1.05)
Signaling	1.62 (1.66)	0.38 (0.87)	3.08 (3.20)	2.54 (3.26)
Adjustment to stimuli	1.46 (2.26)	0.46 (0.78)	1.54 (1.39)	0.38 (0.51)
Visual scanning	0.38 (0.65)	0.00 (0.00)	0.54 (0.88)	0.15 (0.38)
Total driving errors	32.46 (11.60)	13.77 (9.44)	32.00 (12.41)	25.46 (13.26)

Table 2. Between- and Within-Group Differences in Driving Errors at Baseline and Post-Test 1 for Combat Veterans ($N = 26$) by Intervention ($n = 13$) and Control ($n = 13$) Groups.

Analysis	Test statistic	Visual scanning	Lane maintenance	Speeding	Vehicle position	Adjustment to stimuli	Signaling	Gap	Total driving errors
A1	W	159.50	167.00	151.00	156.50	126.50	166.50	161.50	145.00
	<i>M</i> (<i>SD</i>)	0.35 (0.69)	9.31 (5.33)	11.54 (7.56)	1.50 (1.45)	0.96 (1.18)	2.81 (3.18)	2.27 (1.19)	28.73 (13.02)
	<i>p</i> value	.26	.68	.22	.33	.01	.65	.48	.12
A2	W	149.50	125.00	127.00	130.00	152.00	128.00	145.50	110.00
	<i>M</i> (<i>SD</i>)	0.19 (0.49)	9.20 (5.94)	8.62 (6.96)	1.50 (1.65)	0.96 (1.73)	1.00 (1.44)	1.65 (1.23)	23.12 (14.08)
	<i>p</i> value	.10	.01	.01	.01	.20	.01	.11	<.001
A3	W	171.50	151.00	173.50	162.00	158.00	157.00	169.50	172.00
	<i>M</i> (<i>SD</i>)	0.46 (0.76)	11.08 (5.68)	12.12 (7.46)	2.12 (1.77)	1.50 (1.84)	2.35 (2.61)	2.08 (1.16)	32.32 (11.77)
	<i>p</i> value	.83	.22	.93	.50	.39	.35	.77	.87
A4	W	162.50	153.00	137.50	154.50	174.00	125.00	131.50	126.00
	<i>M</i> (<i>SD</i>)	0.08 (0.27)	7.42 (4.95)	7.50 (6.36)	0.88 (0.95)	0.42 (0.64)	1.46 (2.58)	1.84 (1.32)	19.62 (12.76)
	<i>p</i> value	.48	.26	.05	.31	.05	<.001	.02	.01

Note. A1 = Analysis 1; A2 = Analysis 2; A3 = Analysis 3; A4 = Analysis 4; W = Wilcoxon rank-sum test value; Analysis 1: Control baseline versus Control Post-Test 1; Analysis 2: Intervention baseline versus Intervention Post-Test 1; Analysis 3: Control baseline versus Intervention baseline; Analysis 4: Control Post-Test 1 versus Intervention Post-Test 1.

(53.8% for the intervention and control groups), and sniper fire (38.5% for the intervention group; 46.2% for the control group). Because no significant differences emerged for the exposures between the groups, we deduced that their exposure history was equivalent.

Clinical test results showed no significant group differences. The majority of participants had 20/20 vision when corrected, and intact depth perception. Mean cognitive scores from the MMSE were above 29 for each group, indicating virtually no cognitive deficits. Similarly, UFOV scores were Category 1 (lowest risk of potential future crash) for 92.3% of participants, again with no between-group differences. Mean UFOV sub-test scores of both groups were generally better than the cut-off scores (i.e., 500 ms). Visual processing impairment was only identified in two participants: one rated Category 2—low risk (intervention group) and the other rated Category 3—low to moderate risk (control group) for

MVCs. Coordination, measured by finger-to-nose test and toe tap, was within functional limits for the groups.

Table 1 displays the means and standard deviations for driving errors at baseline and at Post-Test 1 for the intervention and control groups. The baseline error with the highest mean scores across both groups was speed regulation, followed by lane maintenance. However, a post hoc analysis revealed that more underspeeding versus overspeeding errors occurred at baseline in the intervention ($M = 7.08$, $SD = 6.10$ vs. $M = 5.23$, $SD = 7.05$) and control groups ($M = 7.31$, $SD = 8.56$ vs. $M = 5.69$, $SD = 7.47$). For the intervention group, mean driving errors decreased for all error types at Post-Test 1. Likewise for the control group, except for gap acceptance, mean error scores decreased for all other driving errors at Post-Test 1.

Table 2 demonstrates the difference in mean driving errors made at baseline and after the intervention for both groups.

Comparisons to detect differences in mean scores, as a result of the intervention, were made four ways (control group against themselves at baseline and Post-Test 1; intervention group against themselves at baseline and Post-Test 1; control against intervention group at baseline; and the control against the intervention group at Post-Test 1), as indicated in the next section.

Analysis 1: Control Baseline Versus Control Post-Test 1

In comparing the mean errors by type made at baseline with the mean errors by type made at Post-Test 1 for the control group, only adjustment-to-stimuli errors decreased.

Analysis 2: Intervention Baseline Versus Intervention Post-Test 1

Upon comparing the mean errors by type made at baseline with the mean errors by type at Post-Test 1 for the intervention group, lane maintenance, speeding, vehicle position, signaling, and total driving errors decreased.

Analysis 3: Control Baseline Versus Intervention Baseline

Upon comparing the control group's baseline versus the intervention group's baseline, no significant findings emerged.

Analysis 4: Control Post-Test 1 Versus Intervention Post-Test 1

Upon comparing the control group's Post-Test 1 scores versus the intervention group's Post-Test 1 scores, the following findings emerged. Even though the intervention group made less adjustment-to-stimuli errors at post-test, compared with their own baseline, it was the control group that demonstrated a significant change (decrease) in these types of errors when compared with the intervention group. However, compared with the control group, the intervention group had reduced errors pertaining to speeding, signaling, gap acceptance, and the total number of driving errors.

Discussion

Similar to other CV studies that mainly report on male participants (Amick et al., 2013; Classen et al., 2011; Hwang, Peyton, Kim, Nakama-Sato, & Noble, 2014; Lew et al., 2011; Plach & Sells, 2013), this study had exclusively male participants. In addition, participants were mainly White and educated. Consistent with findings from Hoge et al. (2004), a considerable number of participants in both the intervention and control groups reported blast exposures due to mortars,

IEDs, and sniper fire. Yet different from the Hoge study, a large number of participants in this study also reported being exposed to motor vehicle accidents.

Clinical test results showed no significant group differences. Moreover, only very mild general cognitive impairment was detected. Thus, while participants reported clinical limitations consistent with their post-deployment status, overall they performed well in physical tasks needed for driving. The findings (Table 1) further show that for both groups, and between baseline and Post-Test 1, a reduction in mean driving error scores occurred. These findings suggest that the intervention group may have benefitted from the OT-DI, while the control group may have benefitted from the TSE sessions. However, when compared with the control group, the intervention group also displayed reductions in error scores across a larger number of driving errors. Interestingly, the speeding errors were related to underspeeding and not overspeeding, as previously noted in the literature (Amick et al., 2013; Classen et al., 2011). In discussion with the evaluators, it seemed that participants' speeding behaviors may have been influenced by being more careful while driving the simulator; however, we do not have empirical data to support this observation.

We also observed (Table 2) that only adjustment-to-stimuli errors reduced for the control group at Post-Test 1, while four types of errors, as well as the total number of driving errors, reduced for the intervention group. The findings from this interim analysis support the OT-DI as efficacious for reducing these types and numbers of errors after Post-Test 1. However, the sustainability and generalizability of this study finding can only be verified upon completion of the study and after the final analyses. Interestingly, no differences were detected between the controls and the intervention groups' baseline testing, suggesting that the groups were equivalent in making driving performance errors. The intervention group made more adjustment-to-stimuli errors when compared with the control group. Perhaps the TSE group heightened their awareness to general stimuli presented in the environment, thereby decreasing this error type. However, the intervention group who received targeted strategies for noticing critical roadway information may not have generalized such information to all environmental stimuli. Overall, the intervention group made fewer errors compared with the controls at Post-Test 1 in at least three (speeding, signaling, gap acceptance) of the driving errors, as well as the total number of driving errors.

This is significant in that speeding and gap acceptance are classified as critical driving errors, which increase the risk of being crash involved (Shechtman, Awadzi, Classen, Lanford, & Joo, 2010). Although signaling is not a critical driving error, one may suggest that it is a very important way of communicating intentions of maneuvers to drivers in lead or following vehicles, and as such communicates information to other road users. Lack of such communication may lead to traffic flow challenges.

Table 3. Between- and Within-Group Differences for Speeding Driving Errors at Baseline and Post-Test 1 for Combat Veterans ($N = 26$) by Intervention ($n = 13$) and Control ($n = 13$) Groups.

Analysis	Test statistic	Total speeding	Underspeeding	Overspeeding
Analysis 1	W	151.00	161.00	172.00
	M (SD)	11.54 (7.56)	7.00 (5.85)	5.70 (7.46)
	p value	.22	.47	.87
Analysis 2	W	127.00	144.00	155.00
	M (SD)	8.62 (6.96)	5.04 (5.35)	3.58 (5.40)
	p value	.01	.11	.30
Analysis 3	W	173.50	171.00	166.50
	M (SD)	12.12 (7.46)	7.19 (7.28)	5.46 (7.12)
	p value	.93	.83	.66
Analysis 4	W	137.50	167.50	148.00
	M (SD)	7.50 (6.36)	3.69 (4.31)	3.81 (5.92)
	p value	.05	.69	.16

Note. Analysis 1: Control baseline versus Control Post-Test 1; Analysis 2: Intervention baseline versus Intervention Post-Test 1; Analysis 3: Control baseline versus Intervention baseline; Analysis 4: Control Post-Test 1 versus Intervention Post-Test 1. W = Wilcoxon rank-sum test value.

Differences in the simulator protocols, heterogeneity among subjects, and categorization of driving errors limit direct comparison of study findings reported by Amick et al. (2013) with these findings. For example, Amick et al. measured speed with 10 sub-categories of error including “driving too slow”; yet in reporting the findings, speeding errors were reported collectively (i.e., underspeeding was not distinguished). However, the literature supports CVs making increased driving errors when compared with the general population (Amick et al., 2013); or as an outcome of “battle-mind” driving (Lew et al., 2010). But, our study shows (Table 1) that CVs are more prone to underspeeding in the driving simulator. This finding may be explained by more cautious driving behaviors when being evaluated, or as a result of “taking their time” as they acclimate to the simulator. Interestingly, no statistical significant differences exist between or within the intervention and control group if speeding is further analyzed in terms of over and under speeding (Table 3).

Limitations

The primary limitation of this study is the lack of blinding for evaluators, as they collected baseline and post-test data, as well as conducting the OT-DI, which may have biased and/or skewed the results. For the control group, the use of video to deliver content versus in-person delivery may have created a Hawthorne effect (i.e., observation, or lack thereof, affects performance). A learning effect may have been present for both groups because the driving scenarios used at baseline and post-tests were the same, and the presence of scripted events (e.g., a car pulling out) was not randomized. Therefore, participants could have anticipated the order of the hazards. That being said, both of the groups were exposed to this

aspect of the protocol, so it potentially did not benefit one group over another. The timing of Post-Test 1 was different for the two groups and resulted in the control group requiring additional time before this post-test could be conducted. Immediate evaluation of the intervention group as compared with (more than 2 weeks) delay could have significantly affected findings, especially as we do not yet have the evidence to demonstrate that the intervention group maintained improvements. Although we have randomized the allocation of participants to the OT-DI (10 CVs with TBI/PTSD and three CVs with orthopedic conditions) and TSE group (seven with TBI/PTSD and six with orthopedic conditions), the difference in the distribution of TBI/PTSD and orthopedic conditions between the groups, in this small sample, is problematic. Moreover, based on the results of this simulator study, no causal inferences can be made to on-road driving performance. As such, the data from the interim analysis need to be interpreted with caution.

Strengths

The OT-DI was focused on enabling CVs to assume their occupational roles in life, of which driving is a powerful facilitator. In this interim analysis of the clinical trial, we followed a blocked randomization scheme for participant allocation to group. Equivalence between groups existed at baseline, as evidenced by no significant differences in most demographics, exposures, clinical tests, and driving errors. Despite conversion to video delivery of the TSE, both the OT-DI and TSE were manualized and executed according to a standard procedure. Finally, this work builds on data from a study of driving performance of 18 CVs with TBI (Classen et al., 2011), a single-subject design study (Classen, Monahan, et al., 2014), and an earlier efficacy study (Classen, Cormack, et al., 2014). As such, the findings of this study further contribute to the temporal plausibility of our assessment and intervention work with returning CVs.

The results of these findings may influence future CV studies, guide policy regarding their driving needs, and inform clinicians for identifying at-risk CVs, as well as providing them with intervention strategies for improving driving performance. These findings are based on comparison data between baseline and Post-Test 1 of the two groups in our parallel arm design. To determine intermediate-term effects, subsequent analyses will compare groups based on results from post-tests 3 months after intervention. In addition, we have not yet addressed state records containing citations and violations that are representative of real-world driving. Such comparisons are planned for a future study.

Implications for Practice

Our study findings have the following implications for practice:

- This study and our prior research with veterans illustrate early empirical support for assessing and intervening with CVs, to reduce their driving errors on a simulator.
- The findings support an evidence-informed approach for using driving simulator-based assessment and interventions.
- The findings provide support for the utility and benefits of an OT-DI for CVs.

Research Ethics

Name of Institutional Review Board: University of Florida Institutional Review Board, Health Science Center Institutional Review Board (IRB)-01. Ethic Committee's reference No. 652-2011.

Declaration of Conflicting Interests

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Intermediate Term Effects of an Occupational Therapy Driving Intervention for Combat Veterans

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BACKGROUND

- Combat veterans (CVs) returning from Operation Enduring Freedom (OEF) or Operation Iraqi Freedom (OIF) have reported experiencing challenges with community reintegration and activities of daily living following deployment, including driving [1].
- Conditions such as mild traumatic brain injury (mTBI), posttraumatic stress disorder (PTSD), polytrauma, deployment exposures, and the presence of risky driving behaviors may contribute to impaired fitness-to-drive in CVs [2].
- I-MAP studies have used driving simulators to address the efficacy of an Occupational Therapy Driving Intervention (OT-DI), including a pilot study where CVs with clinical diagnoses made more speeding and adjustment to stimuli driving errors than healthy controls [3] and a study where CVs made fewer total driving errors at post-test 1 (after receiving the OT-DI) than at baseline testing [4].

PURPOSE

- Based on prior studies [3,4] and the impact of driving difficulty on CV community reintegration, participation and safety, we sought to test an OT-DI after an intermediate time frame, comparing driving performance and errors at baseline to post-test 2 conducted 3 months after intervention.
- This study is the first to examine the efficacy of an OT-DI at the intermediate time period.
- This study compared mean driving error differences among the following four conditions:
 - 1) control group at baseline and post-test 2,
 - 2) intervention group at baseline and post-test 2,
 - 3) control group versus intervention group at baseline, and
 - 4) control group versus intervention group at post-test 2.

METHOD

- We recruited post-deployment OIF/OEF CVs in the North Florida/South Georgia Veterans Health System with reported driving difficulties and diagnoses of mTBI, PTSD, and/or orthopedic injury who had not been medically advised not to drive (exclusion).
- Driving simulation took place in the VA's DriveSafety™ CDS-250 Mobile Simulator engineered into a 2010 Dodge Sprinter van.
- This experimental design involved randomization to intervention or control groups.
- 20 participants (10 per group) who completed all post-tests were included in this preliminary analysis.
- Testing included two simulation drives designed to elicit CV driving difficulty with elements such as roadside debris or pedestrians: 1) suburban, residential setting, and 2) a city/highway setting.

METHOD

- An occupational therapist/driver rehabilitation specialist (OT-DRS) assessed CV's simulated driving for the presence of eight error types shown in Figure 1.
- The intervention group received three approximately hour-long sessions focused on OT-DRS instruction in: remediation of driving errors noted at baseline (session 1), strategies to reduce errors (session 2), and driving the simulator with feedback (session 3).
- The control group received three hour-long traffic safety education sessions.
- Post-test 1 (after intervention) and post-test 2 (three months after post-test 1) used the same procedure as baseline testing.
- This study focused on baseline and post-test 2 results, using a one-tailed Wilcoxon Rank-Sum test to determine the between group and within group significant differences.

RESULTS

TABLE 1. Descriptive Statistics for Demographics

Variable	Control Group (n=10)	Intervention Group (n=10)	Group Differences (p < .05)
Age, M (SD)	36.00 (11.615)	38.60 (7.137)	W = 89.50, p = .26
Gender, n (%)			ns
Male	10 (100.00)	10 (100.00)	
Race, n (%)			Fisher's p = .21
Black or African American	2 (100.00)	0	
White	7 (70.00)	10 (100.00)	
Other	1 (10.00)	0	
Ethnicity, n (%)			Fisher's p = 1.00
Hispanic or Latino	2 (20.00)	1 (10.00)	
Not Hispanic	8 (80.00)	9 (90.00)	
Education, n (%)			Fisher's p = 1.00
Completed High School/GED	1 (10.00)	2 (20.00)	
Some College	6 (60.00)	3 (30.00)	
Associate's Degree or higher	3 (30.00)	5 (50.00)	
Marital Status, n (%)			Fisher's p = .35
Married	5 (50.00)	8 (80.00)	
Divorced	1 (10.00)	2 (20.00)	
Single	4 (40.00)	0	
Living Status, n (%)			Fisher's p = 1.00
Alone	1 (10.00)	2 (20.00)	
With Someone	9 (90.00)	8 (80.00)	

Note: W = Wilcoxon Rank Sum Test, Fisher's = Fishers exact test, ns = not significant

RESULTS

FIGURE 1. Comparison of Mean Driving Errors Between Groups



TABLE 2. Wilcoxon Rank-Sum Test for Within and Between Group Mean Driving Error Differences

Control Group at Baseline/Post-Test 2	Intervention Group at Baseline/Post-Test 2	Control Group vs. Intervention Group at Baseline	Control Group vs. Intervention Group at Post-Test 2
W = 75.00, p ≤ .112	W = 58.00, p ≤ .0001	W = 104.50, p ≤ .493	W = 75.00, p ≤ .011

FIGURE 2. VA Mobile DriveSafety CDS-250 Driving Simulator



DISCUSSION

- Demographic characteristics of the control and intervention groups were similar for key variables such as age and education.
- Two of the four Wilcoxon Rank-Sum analyses reached statistical significance: the intervention group's reduction of driving errors at baseline/post-test 2 and the between group differences of the control group and intervention group at post-test 2.
- The significant reduction in driving errors for the intervention group and significant between group difference at post-test 2 suggest efficacy of the OT-DI when compared to traffic safety education.
- This preliminary analysis lacks the sample size and statistical rigor to make definitive conclusions, however, initial results are promising.
- Establishing an effective OT-DI may lead to increased rehabilitation options for CVs and potentially improve driver fitness post-deployment.

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Institute For Mobility, Activity, and Participation



Combat Veterans' Strategies to Manage Risky Driving and Preferences for Driving Intervention

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BACKGROUND

- Combat Veterans (CV) face an increased risk of motor vehicle crashes leading to injury or death; and have reported driving difficulty that impacts their community reintegration (Plach & Sells, 2013).
- The most common OEF/OIF combat related injuries, mild traumatic brain injury (mTBI), orthopedic injuries, and posttraumatic stress disorder (PTSD), may contribute to unsafe driving.
- Life-saving techniques used in combat such as speeding, straddling the midline to avoid roadside bombs, and making unpredictable lane changes are often difficult to unlearn, and may result in dangerous driving behaviors in a noncombat situation (Lew et al., 2011; Possis et al., 2014).
- Hannold, Classen, Winter, Lanford, and Levy (2013), identified that a CV was influenced by deployment experiences, which affected their perceptions and behaviors.

PURPOSE

The purpose of this study was to gain insight on CV's perspectives of deployment training, driving experiences pre and post deployment, strategies to manage driving behaviors, and preferences for a driving intervention.

METHODS

- Participants enrolled in the efficacy trial, were contacted by phone and invited to participate in the focus group.
- Focus group meeting included three participants and lasted approximately 75 minutes.
- The moderator asked a series of open-ended questions to generate discussion among participants.
- The principal investigator and a trained research assistant transcribed the digital audio recordings verbatim and verified the transcript against field notes, before coding.
- Themes and codes from this analysis were compared to an earlier qualitative analysis within the larger study examining CV's perspectives on driving strategies (McGowan, 2014).

RESULTS

Figure 1. Primary Themes and Supporting Quotes



Figure 2. Triggers impacting CVs' driving



RESULTS

Figure 2. Responses impacting CVs' driving

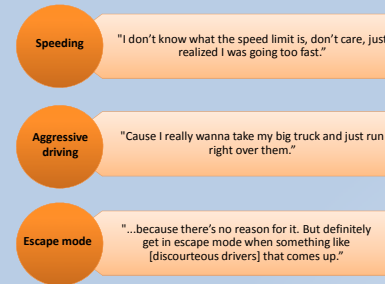
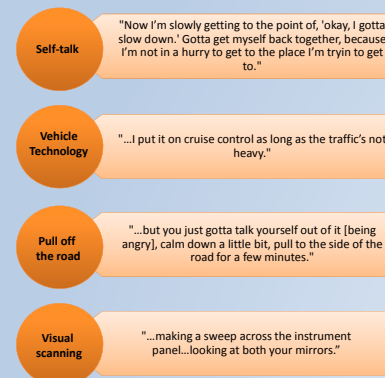


Figure 3. Reported strategies used to manage unsafe driving



DISCUSSION

Data indicate that:

- Participants' learned driving behaviors in combat were reinforced post deployment.
- Despite their ability to recognize unsafe driving behaviors, CVs have difficulty responding appropriately when exposed to triggers.
- The lack of driver re-education training post deployment may impact their ability to curtail unsafe driving behaviors.
- Findings were consistent with related research that demonstrated factors such as anxious driving, triggers, and combat-related experiences, which influenced post deployment driving (Hannold et al., 2013; Hwang et al., 2014).
- This focus group study contributes to the body of literature describing driving performance and driving safety of returning CVs from Iraq and Afghanistan.
- Clinicians working with this population may benefit from study findings in order to understand CVs perspectives on driving, challenges experienced, strategies used to curtail unsafe driving, and preferences for intervention.

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