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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

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. In the 2018-2019 cycle, we added staffing with four additional personnel, all completing their VA credentialing. As of April 2019 we have 20 Veterans enrolled in the five session protocol, half randomized to the occupational therapy driving intervention (OT-DI) and half to the control arm, traffic safety education (TSE). Seven Veterans have completed the protocol and 12 are active in testing. In addition to on-going recruitment and testing, our team has been able to disseminate findings from the efficacy study on a state and national level. This includes 7 journal articles, 1 book chapter, 9 honors theses, and over 20 state and national level presentations. Our examination of real-world driving through analysis of driver license records to determine the level of violations, citations, and crashes in the years pre and post intervention is complete and findings regarding reductions in citations post-intervention are under peer review for potential publication.

Overall, both arms of the study, occupational therapy driving intervention and traffic safety education demonstrate benefits according to our interim analysis – by reducing Veterans driving errors as measured in simulator. Preliminary findings on real-world outcomes also indicate a benefit through reduced traffic violations and citations. In the no cost extension period we will continue testing to confirm these findings with a larger sample of Veteran drivers.

15. SUBJECT TERMS

Randomized Clinical Trial, Intervention, Driving, Rehabilitation, Simulation

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Introduction

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

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

ACCOMPLISHMENTS

- Initiated recruitment in July 2017, following hiring and training of Research Therapist, Dr. Luther King, DrOT and Certified Driving Rehabilitation Specialist
- Enrolled 20 subjects in the study
- Completed testing with 7 subjects
- Have 12 subjects who are active (baseline testing/ and or additional sessions complete with future testing scheduled)
- Developed new community partners for recruitments through events.
- Outreach to VA partners across the North Florida / South Georgia VHS service area.
- Graduated VA WOC status Bachelor of Health Science Honors student, Kasey Clark whose Honors Thesis addressed gender differences in driving errors.

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.

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.

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.

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

- During April 2019 the DOD team held a series of meetings to conduct a SWOT analysis, examining strengths, weaknesses, opportunities and threats with guidance of Dr. Classen. The SWOT analysis facilitated re-alignment and re-structuring for the no cost extension year and allowed us to integrate four new team members (Poojary-Mazzotta, Wersal, Ellison, and Clark). See detailed notes from SWOT meeting - Appendix A.
- As a result of SWOT analysis we are restructuring recruitment with Drs. Poojary-Mazzotta and Wersal as leads. Dr. Poojary-Mazzotta has prior experience coordinating recruitment for an NIH trial. Dr. Wersal, a former Army OT, will focus on Veteran-centric strategies and community networking.
- The number of participants projected will be reduced from 260 to 100 Veteran participants, and similar reduction for caregivers, as stated in Scope of Work submitted with No Cost Extension (dated 12.20.2018).
- In order to focus efforts on two arms of the intervention trial (Occupational Therapy Driving Intervention in simulator and Traffic Safety Education via on-line course), we request to remove Aim 4 from protocol that pertains to testing a sub-group of Veterans on the road. After discussion with DOD, we will submit an IRB revision.

Products

Our scope includes data analysis from "Efficacy of a Driving Program on Safe Community Mobility for Combat Veterans (W81XWH-11-1-0454)". Below find publications and presentations to date. We have four manuscripts in progress for submission during the no cost extension period.

Publications:

Clark, K. (2019). Comparative case-study analysis: Examining driving error differences among male and female veterans post-deployment. (Honor thesis).

Caldwell, K. (2018). Implementing Traffic Safety Education in a Randomized Controlled Trial for Combat Veterans. (Honors thesis).

Classen, S., & Winter, S.M. (2017). Chapter 16. Driving performance of returning combat veterans. In S. Classen (Ed.), *Driving simulation for assessment, intervention, and training: A guide for occupational therapy and health care professionals* (187-199). Bethesda, MD: AOTA Press.

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.

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.*

Classen, S., Monahan, M., Canonizado, M., & Winter, S.M. (2014). An Occupational Therapy Driving Intervention's Utility for a Combat Veteran. *American Journal of Occupational Therapy*, *68*(4), 405-411.

Miller, K. (2015) Combat Veteran Community Integration in a Driving Intervention. (Honors thesis).

Sursky, S. (2015). Intermediate Term Effects of an Occupational Therapy Driving Intervention for Combat Veterans. (Honors thesis).

Szafranski, E. (2015). Understanding Combat Veterans Perspectives on Strategies to Manage Unsafe Driving and Preferences for Driving Intervention. (Honors thesis).

McGowan C. (2014). Combat Veterans' Perspectives on Driving Strategies to Curtail Unsafe Driving. (Honors thesis).

Presentations:

Classen, S., Winter, S., Yarney, A., & Levy, C. Driving Intervention for Returning Combat Veterans: Interim Analysis of a RCT. Poster presented at the Florida Occupational Therapy Association Annual Conference, October 26-27, 2018. Orlando, Florida.

Classen, S., & Winter, S. M. Research Paper. Interim Findings of a RCT: Driving Intervention for Returning Combat Veterans. American Occupational Therapy Association (AOTA) Annual Conference, April 19-22, 2018, Salt Lake City, Utah.

Winter, S.M., Jeghers, M., & Reid, E. Research Paper. Grounded Theory Informing a Driving Intervention Clinical Trial for Returning Combat Veterans American Occupational Therapy Association (AOTA) Annual Conference, April 19-22, 2018, Salt Lake City, Utah

Classen, S., Winter, S. M., Jeghers, M., & Caldwell, K. Workshop. Mixed-Methods Approach to Develop an Occupational Therapy Driving Intervention for Returning Combat Veterans. FOTA Conference, Orlando, Florida, USA November 3-4, 2017.

Classen, S., Winter, S., Yarney, A., & Levy, C. Driving Intervention for Returning Combat Veterans: Interim Analysis of a RCT. 6th Occupational Therapy Summit of Scholars, Boston University, Boston, MA, USA, June 2-June 3, 2017.

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 AOTA Conference, March 30 – April 2, 2017, Chicago, Illinois.

Winter, S. M., Classen, S., Reid, E. Grounded theory on factors influencing driving of combat veterans post-deployment. Presentation given at the 6th Occupational Therapy Summit of Scholars, June 2-3, 2017, Boston University, Boston, Massachusetts.

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 AOTA Conference, March 30 – April 2, 2017, 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 AOTA 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 AOTA Conference, April 7, 2016, 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 FOTA 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.

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 presentation - 39th Annual Assoc. for Driving Rehabilitation Specialists Conference. Louisville, KY, 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.

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

Name: Sherrilene Classen, PhD, MPH, OTR/L, FAOTA, FGSA
Project Role: PI as of March 2018 IRB approval
Researcher Identifier (e.g., ORCID ID):
Nearest person month worked: 3
Contribution to Project: Dr. Classen contributed her expertise in clinical trials, guiding study design and implementation, and planning and overseeing the analyses in conjunction with the PI, the biostatistician and co-investigators. Dr. Classen contributed extensively to the development of manuscripts, the submission of presentations, dissemination of findings, and development of future proposals to extend the work.
Funding Support: Detailed below

Name: Sandra Winter, PhD, OTR/L
Project Role: PI until March 2018, Co-I after March
Researcher Identifier: orcid.org/0000-0002-0317-241X
Nearest person month worked: 6
Contribution to Project: Dr. Winter had overall responsibility for the project execution. She organized the research team and oversaw main research functions. Thus, appoint research staff, obtain IRB approval, manage developmental activities and research activities, collaborate with the project personnel, consultant(s), and the developer of the DriveSafety 250 driving simulator. She supervised the research coordinator, research therapist and research assistants, oversaw data collection, analysis and interpretation, and developed manuscripts, research presentations and reports.
Funding Support: Additional project funded by Florida Department of Transportation

Name: Charles Levy, MD
Project Role: Co-I
Researcher Identifier (e.g., ORCID ID):
Nearest person month worked: 1
Contribution to Project: Dr. Levy's functions as a co-investigator include assisting with recruitment, guiding interaction with VA partners, and educating the team on the rehabilitation needs of the returning combat Veterans. He will participate in recruitment of participants, interpretation of the results, outcome dissemination, and translation of study findings to VA health care settings.
Funding Support: Dr. Levy is a VA physician, salary (5% effort) is paid by VA.

Name: Abraham Yarney, M.E.
Project Role: Graduate Student
Researcher Identifier (e.g., ORCID ID): N/A
Nearest person month worked: 6
Contribution to Project: Primary functions are preparation of study materials for recruitment and testing, recruitment, and data entry. Secondary functions are data management, data audits (with PI), and data analysis overseen by the team and the biostatistician.
Funding Support: N/A

Name: Mary Jeghers, MSOT, OTR/L
Project Role: Graduate Student
Researcher Identifier (e.g., ORCID ID): N/A
Nearest person month worked: 3
Contribution to Project: Primary functions are preparation of study materials for recruitment and testing, distribution of recruitment materials, and data entry. Secondary functions are data management, data audits (with PI), and analysis of data as overseen by the team and the biostatistician.
Funding Support: N/A

Name: Shabnam Medhizadah, MS
Project Role: Graduate Student
Researcher Identifier (e.g., ORCID ID): N/A
Nearest person month worked: 5
Contribution to Project: Primary functions are preparation of study materials, screening participants, recruitment, and participant payment.
Funding Support: Additional project funded by Florida Department of Transportation

Name: Katelyn Caldwell, BHS student (Graduated on May 5, 2018)
Project Role: Honors Student / Research Assistant
Researcher Identifier (e.g., ORCID ID): N/A
Nearest person month worked: 6
Contribution to Project: Primary functions are preparation of study materials for recruitment and testing, distribution of recruitment materials, and data entry.
Funding Support: N/A

Name: Kasey Clark, Bachelor of Health Science Honors student
Project Role: Honors Student / Research Assistant
Researcher Identifier (e.g., ORCID ID): N/A
Nearest person month worked: 3
Contribution to Project: Primary functions are preparation of study materials for recruitment and testing, distribution of recruitment materials, and data entry.
Funding Support: N/A

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

Paralyzed Veterans of America (Classen) 6/1/19 – 5/31/20 .96 Calendar
Total Cost: $50K
Perceptions of Individuals Living with Spinal Cord Injury and Disease regarding Autonomous Vehicles
Goal: To elucidate the perceptions of individuals living with a Spinal Cord Injury and/or Disease before and after riding in an autonomous shuttle to understand their values, hesitations, and beliefs related to autonomous vehicles.

DOT and UF Transportation Institute (Classen) 8/15/181 – 2/28/20 1.2 Calendar
Total cost: $220,000.00
UF and UAB's Demonstration Study: Older Drivers Experiences with Autonomous Vehicle Technology
Goal: To examine and quantify the older drivers' perceptions, values, beliefs, and attitudes, before and after "driving" a simulator (Level 5, SAE Guidelines) and after driving a highly autonomous vehicle (HAV) (Level 5, SAE Guidelines).

FL Dept. Transportation Highway Safety (Winter) 10/9/18 – 9/30/19 1.8 Calendar
Total Costs: $113,093K
Teen Distracted Driving Education Program
Goal: Implement a computer based training program to reduce distracted driving in teens.

Florida Department of Transportation (Classen) 10/4/18 – 9/30/19 .12 Calendar
Total Costs: $188,250K
Aging Road User Information Systems
Goal: Launch an interactive GIS mapping system for Florida's older road users.

NIH (NCMRR) K-12 (Ottenbacher) 9/1/17 – 8/31/22 .24 Calendar
Total cost: $1M ($715K x 5 years)
Rehabilitation Research Career Development Programs (RRCD)
Goal: The RRCD educates and trains future rehabilitation scientists in occupational and physical therapy. Role: Associate Program Director, Executive Committee, UF

HUD CFDA# 14.536 (Ahrentzen) 9/1/17 – 8/31/20 .24 Calendar
Total cost: $531K
Title: The Repurpose Project
Goals: To develop and test repurposed fixtures and interior layouts of prototypical SSAH for accessibility, cost and attractiveness, for different occupant types. 2) To determine the most effective means to convey the findings as a decision support tool to a variety of potential users. Role: Co-PI (Classen)

Department of Veteran's Affairs (Ahrentzen) 4/2/18 – 6/30/19 .12 Calendar
Total cost: $200K
Title: Testing CODY
Goal: Testing an Immersive Technology Tool for Experiencing and Assessing Home Modifications for Veterans with Movement Disabilities and Disorders Role: Co-PI

What other organizations were involved as partners?

1) Organization Name: Veteran Affairs / North Florida – South Georgia VHS
Location of Organization: Gainesville, Florida
Partner's contribution to the project:

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

Special Reporting – Quad Chart

Appendices.

A: SWOT Analysis Notes

B: Products

a) Publications
   a. Thesis by K. Clark
b) Presentations
   a. Poster by K. Clark - as presented April 2019
   b. Abstract -Classen et al. - FL OT Assoc. (FOTA) Annual Conf. Fall 2018
   c. Poster - Classen et al. - as presented November 2018 at FOTA

C: CONSORT diagram/Flowchart of Subject and Proxy Enrollment (as of May 2019)

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

Award Number – W81XWH-15-1-0032

PI: Classen, Sherrilene **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=100 Veterans and 100 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: Testing of randomized subjects in progress with 20 enrolled, 7 of whom completed protocol and 12 active. Veteran team member has established new community connections/ outreach. Baseline testing scheduled for newly enrolled participants in June.

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**

Updated: 4/14/2019

Goals/Milestones

CY14 Goal – Refine intervention - DONE

❑ Complete user evaluation of simulator drives/ integrate into intervention

CY15 Goals - Evaluate group differences – TESTING in 2019

☐ 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 – TESTING in 2019

☐ 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 - MANUSCRIPT SUBMITTED in 2018 from FL DMV reports

Comments/Challenges/Issues/Concerns

- Re-organized under Dr. Classen (PI). Team members added for recruitment, and two Occupational Therapists/ Driving Rehabilitation Specialists to increase testing capacity. No cost extension granted.

Budget Expenditure to Date : $803,744 as of 4/14/2019

Effectiveness of a Driving Intervention on Safe Community Mobility for Returning Combat Veterans
SWOT Analysis Meeting Notes

Meeting attendees:

- Dr. Classen
- Dr. Winter
- Dr. King
- Dr. Poojary-Mazzotta
- Dr. Wersal
- Mary Jeghers
- Shabnam Medhizadah
- Abraham Yarney

Meeting Dates: March 12, 13, 18, 26; April 2nd

Objectives of the SWOT Analysis:

- Overview – analyzing process
- What is going well/what is not going well
- Re-organizing
- Achieving our mission
- Strengthening team work
- Developing new strategies
- Refocusing

Ground Rules:

- Honesty (judgement free and evaluate issues)
- Critical but constructive
- Highlighting (strengths and weaknesses)
- Communicate and connect
- Realism
- Review

SWOT Analysis:

Strengths

What makes our grant the top tool for consumer needs?		
Dr. Winter's Team	Dr. PM's Team	Dr. Classen
One of a kind	Thorough IRB process for specialized population	CDRS, Medical monitor, Chief of physical medicine and rehab for NF/SG VHS
Filling a gap and answer critical question	Well established infrastructure (grants core/UF)	
Translational/moving driving simulation science from lab to field	Track record/years experience with traffic safety research	
Practical application/tools for the CV	Study design promotes participation	
OT driven but not OT specific	Geographical location – FL leading for deployment	
Relevant/enhances current driving rehab in military & veteran healthcare settings	Meeting the vets in their environment	
	Target for specialized population	

What are the cutting edge features?		
Dr. Winter's Team	Dr. PM's Team	Dr. Classen
Mobile simulator	Mobile simulator	
Diverse team/multiple expertise	Experienced team and leaders/diverse team	
CDRS/vehicles	Clinical expertise to hand simulator sickness	
Capacity to successfully complete the study	Parameter of the network	
	Professional establishment to disseminate scientific findings	

What are the novel capabilities to set us apart?		
Dr. Winter's Team	Dr. PM's Team	Dr. Classen
UF/VA collaboration	Can be related to pilot study – more rigor	
I-MAP/CINDRR collaboration	Unique to the nation	
17 years of driving research/11 years of veteran focused research	Continual growth/diverse perspective from multiple team members	
Focus on dissemination – 9 peer review articles	Current team member who is a returning CV	
First ever RCT with focus on returning CV		

Weaknesses

What aspects of our team or project have room for growth?		
Dr. Winter's Team	Dr. PM's Team	Dr. Classen
More organized – managing calls, broken communication	Time management	
Defined roles – dedication to the goal, protected time	Recruitment	
Leadership – skills for delegation and holding individual accountable	Management/channelizing tasks	
	Communication	
	Stream line process/more efficiency	
	Accountability	

What part of our team or project can be improved to strength our research?		
Dr. Winter's Team	Dr. PM's Team	Dr. Classen
Recruitment – voicemail/cellphone	Structured weekly follow-up	
Adherence	More aggressive with individual roles and responsibilities	
Team communication	Specific roles and responsibilities	
Participant communication – timely response to participant	Identify short term goals	
Systems – larger team, overlapping roles, breaking down task into multiple smaller ones		

What aspects of our team project are a concern?		
Dr. Winter's Team	Dr. PM's Team	Dr. Classen
Broken communication	Recruitment	Too much peripheral involvement from the VA
System/procedures – lack of efficiency	Clarity with past processes	
Working blind - task focused vs. mission focused	Respective time commitment	
No big picture	Understanding population needs/culture	
Time commitment	Team members assigned with too any roles	
Avoid attrition – complex study design		

Opportunities

- DOD
  - Knowledge of solutions for elevated driving risk of a CV
  - Dissemination and translation – starting to change
  - Evidence base for intervention
  - Simulator and intervention drives and protocol
  - Craves information that is data driven, credibility, and tangible data
- VA/Medical Health System and Veteran's
  - Find solutions of driving concerns
  - Resources are knowledge (TSE) or skill set (OTDI) or financial support
  - Resources available to the veterans and their family members
  - Skills - CDRS, OTs, concern for veterans, HSP
  - Opportunity to set a model for other states to use
- OT/CDRS/DRS
  - Crave solutions and guidelines for CV clients
  - Tools – OTDI
  - Knowledge – applicability vets and others
- Researchers
  - Tools - Example of RCT
  - Feasibility and fidelity - how to Knowledge
  - Lessons learned
  - Skills – what it takes in a team, diversity, experience
- DMV
  - Overall safety of FL population
  - Knowledge – data on issue (#s, cause, solutions)
  - Skills – driving research include epi/secondary data and intervention
  - Tool – policy guidance, CDRS, consulting

- University of Florida
    - Craving to be Top 5 university and our research helps boost this
    - Rigorous research
    - Functioning computers, simulator, more grants, publications
- OT profession
    - Craving recognition of unique role to foster performance
    - Skills – OT research, dissemination, grants, and collaboration all leading to clinical guidelines
- DriveSafety
    - Can market their scenario and sell it to others
    - Gain knowledge associated with driving
- CINDRR
    - A need for assistance in rural health - leading to huge opportunities for CV in rural areas
- Traffic Safety Education
    - Can either adapt of use our work to promote their TSE programs
    - Promotion of business
    - Ways to enhance education
- IRB
    - Our study can further educate the IRB about driving
      Able to use our research to help guide their practices when they receive driving studies
    - One of our team members can serve on the IRB to review driving grants or as an external member reviewing grants
    - Ethical treatment of all individual in study

Threats

What obstacles can challenge our success?		
Dr. Winter's Team	Dr. PM's Team	Dr. Classen
CV related driving risk declines	Lack of funding to support services – policy and investment	
Changing DOD/VA priorities	Lack of CDRSs to address CV needs	
Loss of importance of our study	Competing programs (e.g. transitional training)	
Telehealth/competing interventions (e.g. mental health counseling)		
Resource intensive (time, money, specialized expertise)		

Problem Solving: Gap Analysis

- Present
    - Lack of responsibilities/roles
    - Communication vs connection
    - Difficulty to access participants/culture/stakeholders
    - Van malfunction
    - Leadership – mission focused
    - Sponsor LT plans – unsure
    - Realistic time commitments
    - Staffing issues – Abraham leaving and Dr. King only available for limited period
- Future (until 2020)
    - Recruitment – 5 individuals randomized into the study per month, not acceptable for any less than 5, this will lead to a N=84
        - Biweekly meeting – Thursdays for 30 min - 1-hour meeting
        - 5 things on the meeting agenda that we work towards
    - Clear participant tracking to ensure adherence - CONSORT diagram updated on weekly basis
    - Commitment to leadership
    - Role execution with optimal knowledge and support
    - Manuscripts – Final drafts by April 2020
        1. Recruitment - practical strategies for increasing recruitment in an RTC (Dr. PM leads)
        2. Real world driving outcomes from a OTDI – traffic records, interim analysis at 50 participants (Dr. Classen leads)
        3. FTDS and CVs once we enroll 60 people (Shabnam leads)
        4. Manualized intervention (Dr. Winter leads)
            - MJ and JW take notes throughout and reflections to assist with MS to contribute
    - Adequate staffing - Addition of new member
        - CDRS
            - Baseline testing and intervention based on research protocol – MJ and JW
        - Another staff individual who could help with TSE

Follow up Workforce Strategy Meeting

- Workforce Strategy
    - Glue - communication and connection daily, and we need to become vulnerable and respect each other's vulnerability
    - Funding – approved for one more year
    - Areas to focus efforts for each team member – the lead person for the positions listed below are not the sole person for that task but the leader
        - Recruitment – PP-M, JW as secondary
            - Excel spreadsheets
        - Marketing – PP-M, JW as secondary
        - Equipment - LK
        - Contacts (phone screening for enrollment) - SM
        - Enrolling
            - Baseline - LK, MJ, JW
            - Random allocation - MJ
                - CONSORT guidelines (corresponding with all team members doing OTDI and TSE), Individual tracking on a horizontal scale, CONSORT vertical being full group of participants - MJ
                - Central scheduler to manage all veteran appointments both OTDI and TSE- MJ
                - Experimental group (OTDI) – LK, MJ, JW
                - Control group (TSE) - SM
            - Post-test 1 - LK, MJ, JW
            - Post-test 2 - LK, MJ, JW
        - Caregiver involvement - LK, MJ, JW
    - Consultant to train MJ and JW – MM to visit and train
    - Administration – SW, AY as a resource if needed, work study student, or Jaewon Kang
        - Purchase and prep folders and supplies
        - Payments for participants
        - Reporting for DOD and IRB
        - IRB revisions and monitor
        - Data entry at the VA
        - Contact with medical monitors
        - Sponsor communication
    - Meetings - SC
        - Coordinator and agendas - SC
        - Documentation
            - Excel – PP-M present
                - Recruitment
                - Marketing

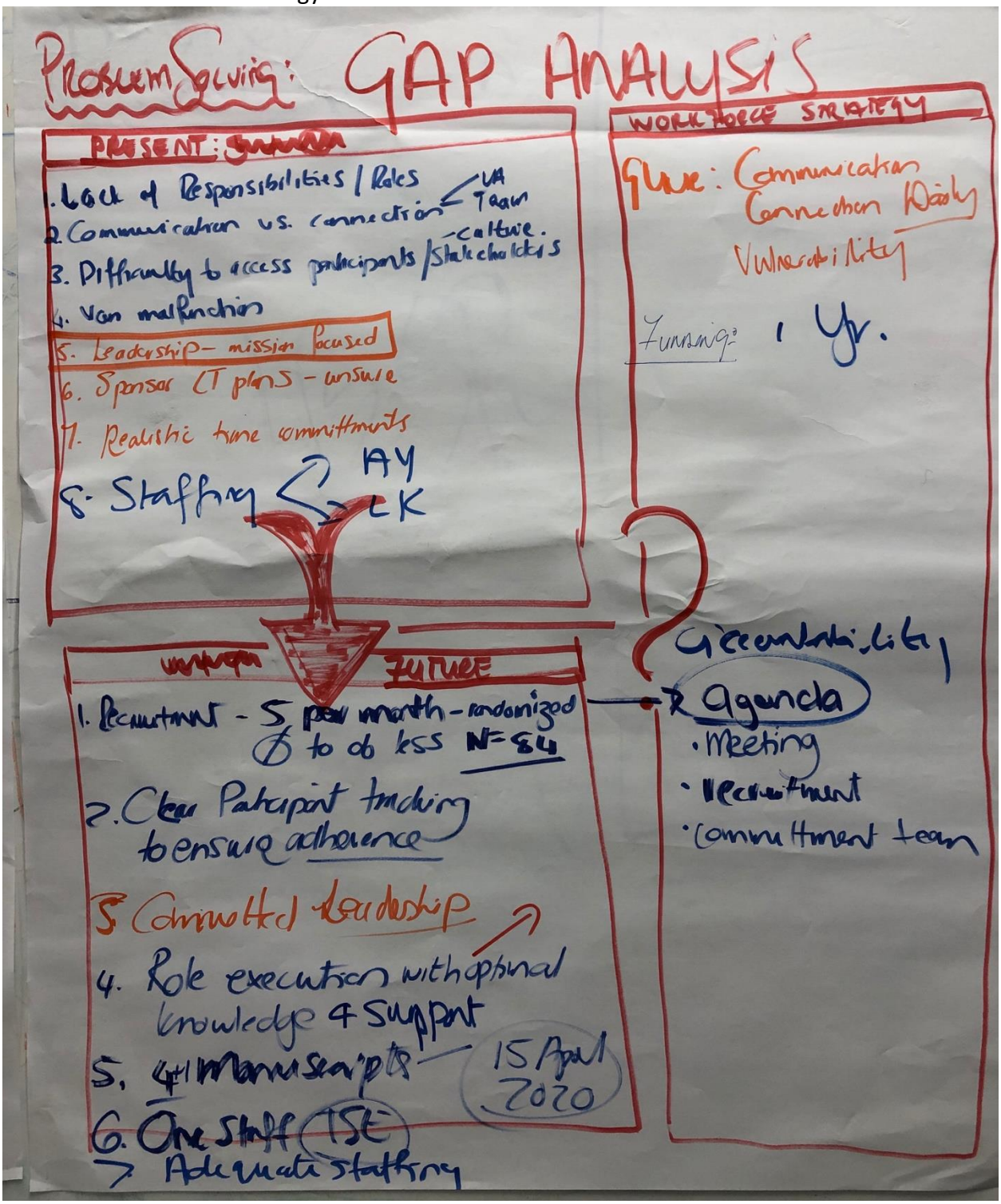
        - CONSORT – MJ present
            - Contacts
            - + screened participants
            - Enrolled participants
        - Administrative – SW present
        - Scientific process and dissemination – SC present
        - TSE and screening updates – SM present
    - Manuscripts – SC
        - Additional notes:
            - FTDS – what is predictive to what is happening in real world to simulation
    - Future funding - SC
    - Conference presentation – SC

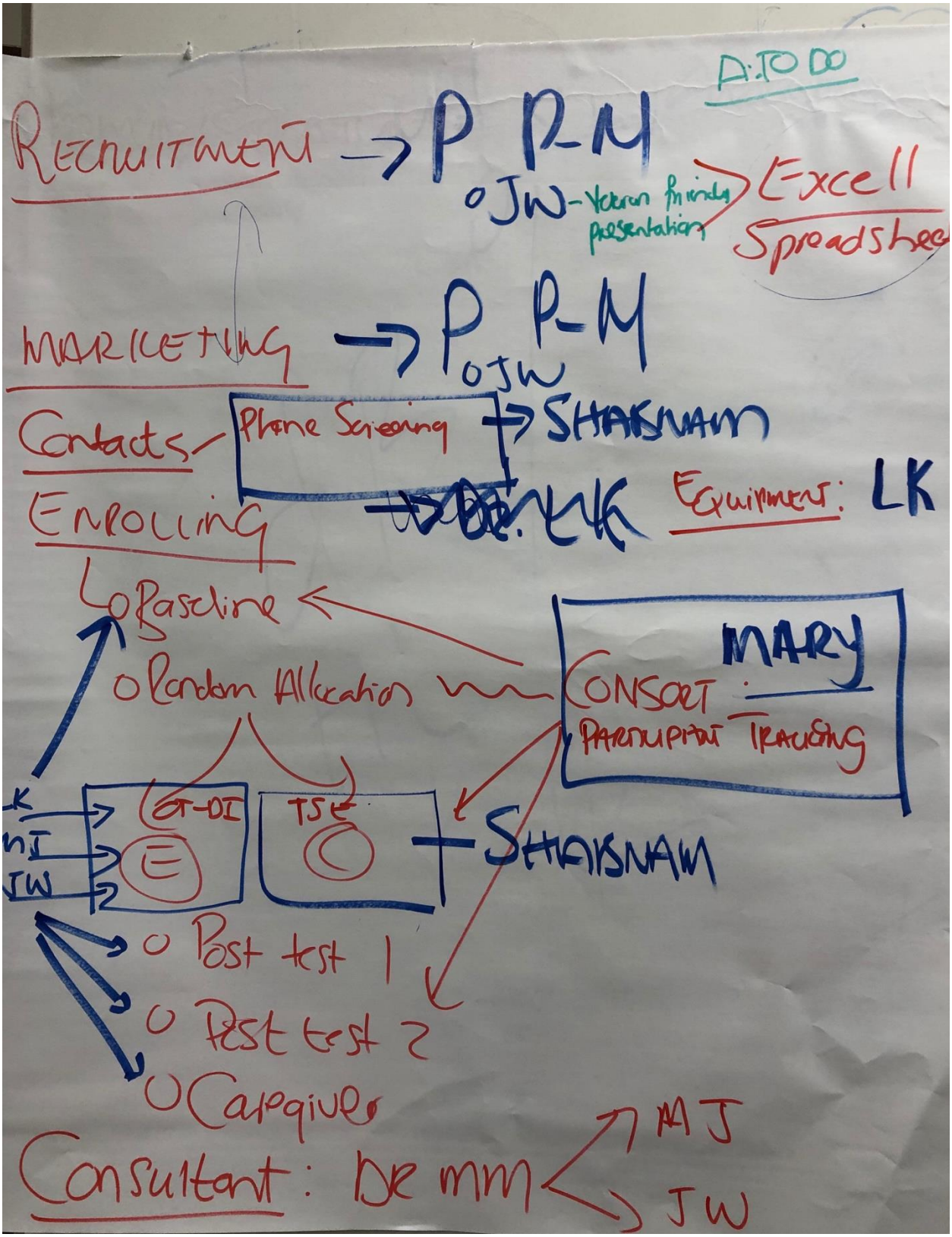
Closure Meeting

- Instead of on-road testing, we will continue to evaluate traffic records. The on-road testing portion of the study is too complex at this point.
- Action steps:
    - PPM and JW need access to the P drive – SW
    - Consolidation meeting with our partners for VA and DOD - SW
    - Recruitment – PPM and JW
        - Contact participants via mail instead of just phone
        - JW will work on the recruitment PowerPoint to make it more veteran centric
        - Schedule a recruitment meeting (SC, PPM, SW, JW) – happen next week after AOTA – 11th an hour booked? - MJ
    - Equipment - LK
        - JW and MJ email Nick to get all team members on the driver training for the motor pool, and JW and MJ need additional training for the simulator van
    - Screening and enrollment - SM
        - Preparing folder for documents
        - Carrying cell phone
    - Consort and scheduling:
        - Arrange for all outstanding participants to get scheduled – LK and MJ
        - Communication between MJ, LK, JW- work with LK to figure out the best way to manage (Wednesday availability) - MJ
        - Document needs to be created for scheduling purposes
        - Meeting with Abraham to review and learn about the CONSORT - MJ
    - OTDI
        - Training for JW and MJ with Miriam Monahan in May
    - Specific tasks for Dr. Winter

        - Work study student training
        - DOD/VA meeting set
        - Recruitment meeting
        - IRB protocol changes
    - Specific tasks for Dr. Classen
        - Scheduling the agenda and documents for meetings
        - Working with Miriam to get training done for MJ and JW
        - Manuscripts

Additional:
Pictures of Workforce Strategy




A:TO DO
RECRUITMENT → P P-M
oJW- Veteran Priority presentation
Excell Spreadshee
MARKETING → P P-M oJW
Contacts-
Phone Screening → SHAKNAM
ENROLLING
Equipment: LK
oBaseline
oRandom Allocation
MARY
CONSORT
PARTICIPANT TRACKING
GT-DI
TSE
SHAKNAM
Post test 1
Post test 2
Caregiver
Consultant: Dr mm
MJ
JW

Administration — S.W. ← SW Kang Workstudy Student.

(AY) - Resource

E.g.
- o Folders
- o Payment
- o Reports
- o IRB
- o Data Entry
- o Medical Monitors
- o Sponsor Communication

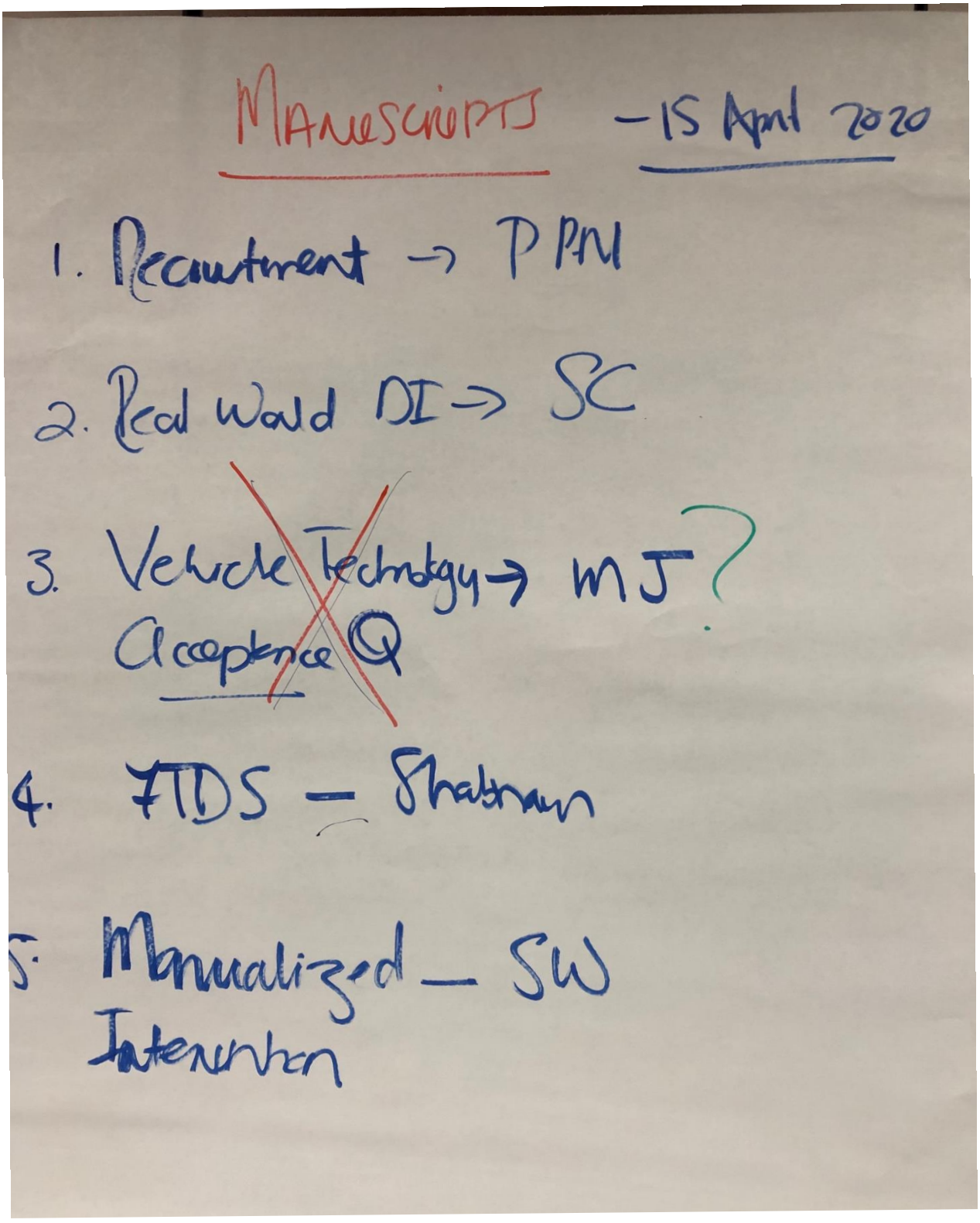
Meetings :- SC SE

- o Coordinator :- SC
- o Documentation:
  - ① Recruitment / Marketing Contacts ⟩ Excel — PM
  - ④ Screened Enrolled ⟩ ② Consort — MJ
  - ③ Admin SW
  - ④ Sc. process / Diss SC
  - ⑤ TSE Shadow Screening.

Manuscripts: SHERRILENE

Future funding: SHERRILENE

Conference Presentations: SHERRILENE


MANUSCRIPTS -15 April 2020
1. Recruitment → PPM
2. Real World DI → SC
3. Vehicle Technology → MJ ?
Acceptance Q
4. FTDS — Shaktman
5. Manualized — SW
Intervention

Comparative Case-Study Analysis: Examining Driving Error Differences among Male and Female Veterans Post-deployment

Kasey Clark

University of Florida

Mentor: Sandra Winter, PhD, OTR/L

Abstract

The number of women in combat is increasing, yet the impact of gender on deployment-related medical conditions and related driving fitness is not known. In 2017 Classen et al. assessed efficacy of a simulator-based occupational therapy intervention addressing CVs' driving fitness. We sought to extend these findings to identify gender differences in driving errors and factors affecting driving fitness, such as comorbidities. From our prior work, 3 participant pairs were identified for case comparison based on gender and age, matching male CVs ages 34, 37, 38 with female CVs ages 25, 33, 39. Using descriptive statistics, we analyzed number/ type of driving errors, and comorbidities. Comorbidities included Traumatic Brain Injury (3 males/ 1 female), orthopedic issues (2 female), and Post Traumatic Stress Disorder (2 males, 3 females). Lane maintenance was the most common driving error for males (M= 8.33, SD$\pm$ 7.64), versus overspeeding for females (M= 7.00, SD$\pm$ 7.00) but total driving error means were similar (males M= 27.00, SD$\pm$ 8.72 versus females M= 24.00, SD$\pm$ 6.93). Despite sampling limitations, this study explores a critical topic as understanding gender differences in post-deployment driving can inform intervention. Future analysis will examine assess clinically relevant gender differences in response to intervention.

Introduction

Since 2001, over 2 million service members were deployed to Afghanistan and Iraq during Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OIF), and Operation New Dawn (OND) (Vogt et al., 2011). Compared to the demographics of prior U.S. wars, OEF/OIF/OND are associated with a rise in female service members, with female combat exposure experienced at higher rates than previously recorded (Vogt, et al., 2011). Increased presence of females in combat roles is a result of a progressive generational shift toward parallel roles of males and females in warfare (Vogt, et al., 2011). Despite similarities in combat roles of males and females, the post-deployment health of returning Combat Veterans (CVs) from OEF/OIF/OND is known to differ between genders (Hoge, Clark, & Castro, 2011). These differences are seen in rates of, and symptoms experienced with, post-deployment mental health disorders such as Post-traumatic Stress Disorder (PTSD), anxiety disorders, and depression (Fulton et al., 2015). Similarly, community reintegration is known to differ between male and female CVs (Mattocks, Haskell, Krebs, Justice, Yano & Brandt, 2012). One aspect of community reintegration is community mobility, including driving. Driving elicits a sense of independence in accessing community resources that is often instrumental in community integration. Driving fitness is a concept that measures an individual's overall capacities and skills in factors related to driving, such as vision, motor and somatosensory function, and cognition (American Geriatrics Society & A. Pomidor, Ed., 2016). Driving fitness of CVs may be impacted by deployment-related medical conditions, including those impacting mental and physical health (Classen et al., 2017), and deployment history (Woodall, Jacobson, & Crum-Cianflone, 2014). CVs face an increased risk in being involved in motor vehicle crashes (MVC), partly due to decreased driving fitness and battlemind driving behaviors. Battlemind driving

behaviors are dangerous, defensive and offensive driving tactics engrained during combat and carried into civilian life (Classen et al., 2017).

Aims

Prior research has examined driving fitness, driving errors and crash risk of CVs. However, whether important differences exist in post-deployment driving between males and females; differences that may impact their driving fitness, crash risk, and community reintegration; has not been described or defined in the existing literature. In order to address this gap, this study will analyze differences in errors made between males and females who participated in the DOD funded study: "Efficacy of a Driving Program on Safe Community Mobility for Combat Veterans" (Classen et al., 2011) and the randomized controlled trial: "Effectiveness of a Driving Intervention on Safe Community Mobility for Returning Combat Veterans" (Classen et al., 2017), an extension of the former. Specifically, the research question for this thesis is: Are there observable differences in driving errors, by number and type, made by males and females who have participated in the efficacy and effectiveness studies?

Method

Design

We employed a comparative case-study design. Three pairs were identified based on age, each including a male and female CV.

Data Analysis

Descriptive statistics were used to analyze demographic data, exposure history, health statistics, and driving errors made between groups. In analyzing demographic data variables of gender, race, education, and marital status were observed. In analyzing exposure history, primary blast exposure, body part injured, and secondary injuries were observed. For health-related

statistics, comorbidities including Traumatic Brain Injury (TBI), orthopedic issues, and Post-Traumatic Stress Disorder (PTSD) were observed, along with a span of musculoskeletal disorders, neurological diseases, respiratory diseases, heart diseases, and acuity of vision. For driving errors, the eight errors that were analyzed are: speed regulation, lane maintenance, visual scanning, gap acceptance, adjustment to stimuli, vehicle positioning, signaling, and the total number of errors. Speeding and gap acceptance are classified as critical driving errors, errors which are associated with increased crash risk (Classen, et al., 2017).

Results

Demographics

Participants included 3 males (ages 34, 37, 38) and 3 females (ages 25, 33, 39). The demographic statistics for CVs (N=6) demonstrated that the majority of CVs were White (2 males, 2 females), with CVs of Black or African American and Asian race also represented. Overall, the females (n=3) had higher levels of education. For education, females reported completion of a bachelor's degree and a master's degree (n=1). Out of the males, 2 reported some college education and 1 reported an associate's degree. Demographic statistics indicated all 3 males were married while 1 female was divorced and 2 were single.

Exposures

Females had a higher occurrence of primary blast exposure in 4 out of 5 categories observed (improvised explosive device (IED), grenade, land mine and sniper fire). The most common blast exposure in both groups was primary blast exposure due to mortar (2 males, 2 females).

Health-related Statistics

In this comparative case analysis, the 6 CVs reported similar levels of musculoskeletal disorders and similar visual acuity. More male CVs reported neurological disorders, including TBI. Neurological disorders unique to male CVs include peripheral neuropathy and peripheral nerve disorder. Within this category, all male CVs reported sleep disorders vs. 1 female. More female CVs reported PTSD (2 males, 3 females) and orthopedic issues (0 males, 2 females). Female CVs had higher levels of heart diseases, respiratory diseases, urinary diseases, diseases affecting vision, and glandular diseases. Conditions unique to female CVs include circulation trouble, asthma, urinary tract infection, diseases affecting vision, thyroid or gallbladder problems, brain disorder (TIA, brain tumor, or cerebral atrophy) and cancer.

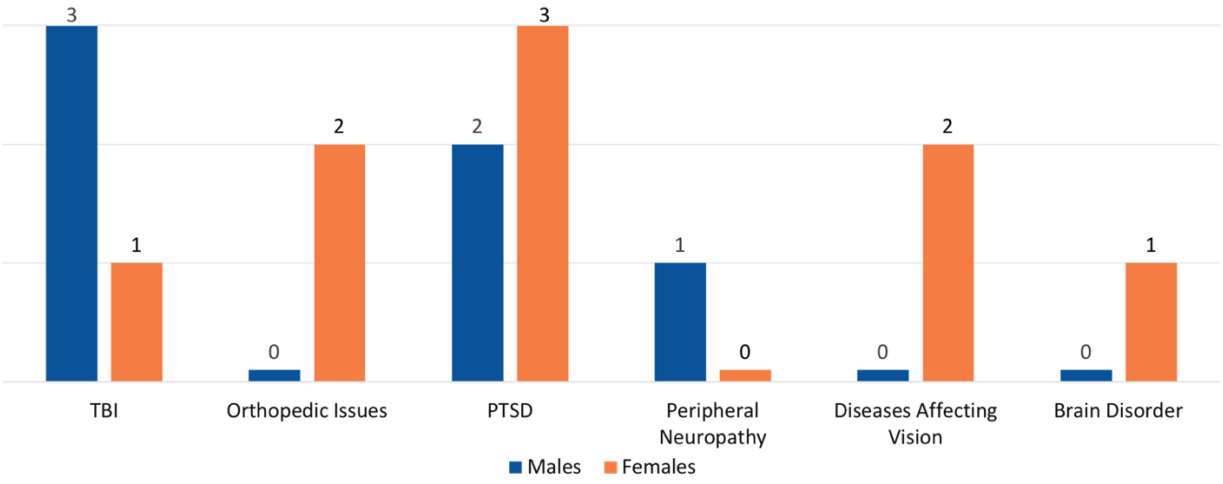


Figure 1. Reported Co-morbidities by Gender

Driving Errors

Collectively, the most predominant driving errors were underspeeding (sum=34.00, M= 11.34) and lane maintenance errors (sum= 32.00, M= 10.67). For male CVs, lane maintenance was the most common driving error (M= 8.33, SD± 7.64). In contrast, overspeeding was the

most common error for female CVs (M= 7.00, SD± 7.00). Despite these differences, overall results for driving errors among male and female CVs were similar (males range= 17.00-33.00, M= 27.00, SD± 8.72) (females range= 20.00-32.00, M= 24.00, SD± 6.93). For adjustment to stimuli and gap acceptance errors, the means and standards deviations were the same for both groups (M= 1.00, SD± 0.58).

Table 1

Gender Comparison of Driving Errors by Number and Type

Error:	Visual Scanning		Lane Maintenance		Under-speeding		Over-speeding		Vehicle positioning		Adjustment to stimuli		Signaling		Gap acceptance		Total driving errors	
Gender	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Min	-	-	-	-	3	3	2	2	1	-	-	-	2	-	-	-	17	20
Max	-	3	15	5	7	11	4	15	3	3	2	2	5	3	1	1	33	32
Mean	-	1.67	8.33	2.33	4.67	6.67	2.67	7.00	2.00	1.67	1.00	1.00	3.00	1.67	0.67	0.67	27	24
Std. Dev.	-	1.53	7.64	2.52	2.08	4.04	1.15	7.00	1.00	1.53	1.00	1.00	1.73	1.53	0.58	0.58	8.72	6.92

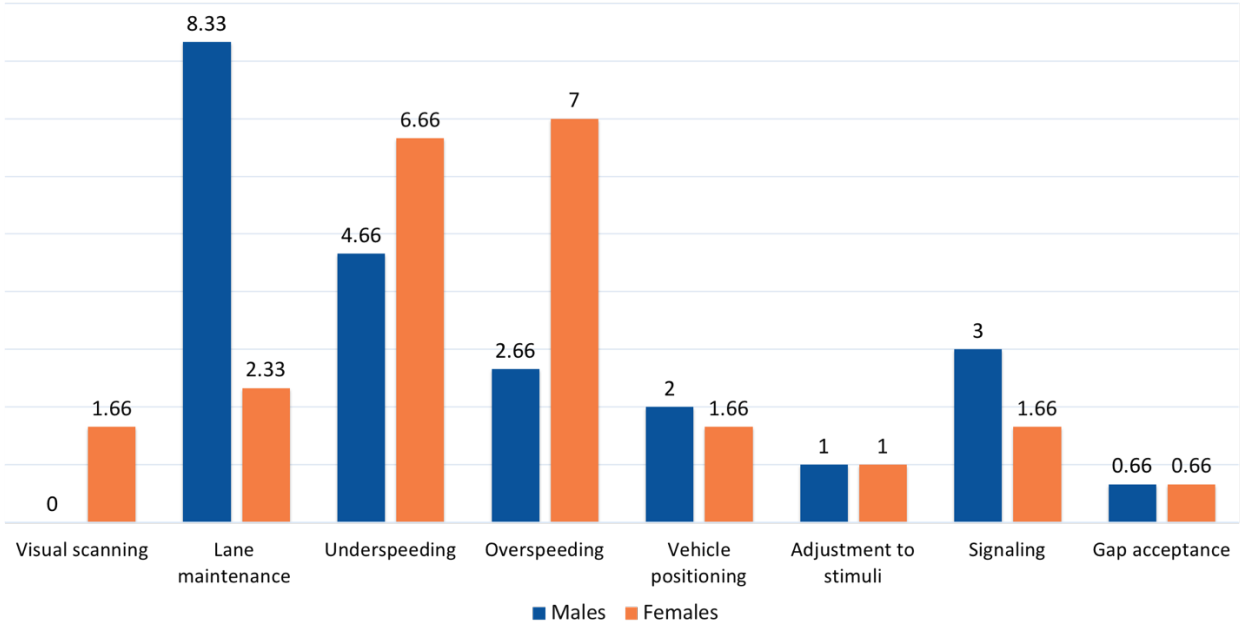


Figure 2. Gender Comparison of Driving Error Means by Type

Discussion

We sought to compare data between male and female CVs in our ongoing study to explore potential differences that may impact driving fitness, crash risk, and community reintegration. To our benefit, the mean age of both groups (males M= 36.67, females M= 34.33) was similar. We found experience of primary blast exposure and total number of comorbidities was similar between groups. The greatest differences were seen in education, marital status, and comorbidity type. In this case-comparison, 2 female CVs reported being single and 1 female CV reported being divorced, while all 3 male CVs reported being married. This is a finding of interest as marital status is known to impact driving. According to a 2004 cohort study including 10,525 participants, never-married individuals had twice the risk of being injured as a driver after adjusting for age, sex, and study cohort (Whitlock, Norton, Clark, Jackson, & MacMahon, 2004), which highlights a correlation between marital status and driving behaviors. For comorbidity type, male CVs had higher rates of TBI, peripheral neuropathy, and peripheral nerve disorder. According to Schultheis and Whipple, long-term symptoms of TBI include various physical, cognitive and behavioral impacts that affect everyday activities of living, such as driving (2014). Additionally, peripheral neuropathy is known to affect driving due to reduced sensation and proprioception in the limbs. Specifically, peripheral neuropathy can impact ability to operate a steering wheel or gauge pressure on foot pedals (Graveling & Frier, 2015). Female CVs had higher rates of orthopedic issues, PTSD, diseases affecting vision, and brain disorder. In CVs from OEF/OIF/OND specifically, PTSD has been associated with aggressive driving behaviors (Kuhn, Drescher, Ruzek & Rosen, 2010). In our previous work (Hannold, Classen, Winter, Lanford & Levy, 2013), we highlighted a relationship between PTSD and unsafe driving

behaviors of CVs. For example, PTSD symptoms of hypervigilance may elevate fear of roadside bombs or suspicious vehicles and provoke CVs' unsafe driving behaviors. Similarly, female CVs' higher rates of diseases affecting vision is of interest since poor vision has been correlated to higher accident rates in civilians (Charman, 1997). Neurological disorders are also known to impact driving fitness, as the odds of passing a driving evaluation decrease as the severity of brain disorder increases (Schanke & Sundet, 2000).

Our findings illustrated gender differences in driving error type. For male CVs, lane maintenance (M= 8.34) errors were the most common. This category had the highest mean out of all driving errors observed in this case comparison. For the female CVs, overspeeding (M= 7.00) and underspeeding (M= 6.67) errors were the most common. This is notable because speeding is classified as a critical driving error (Classen, et al., 2017). Interestingly, our female CVs had higher mean speed related errors. This contrasts findings that civilian males are more likely to overspeed (Cestac, Paran & Delhomme, 2011), receive a traffic citations (Lonczak, Neighbors & Donovan, 2007), be involved in MVCs (Özkan & Lajunen, 2006), and have a higher fatal MVC risk (Massie, Campbell & Williams, 1995).

Limitations

The primary limitation of this study is its small sample size (N= 6). Resultingly, tendencies between gender, experiences, and health cannot be correlated to the type of driving errors observed in each category. Due to the small sample size, a matched pair has a greater gap in age than they would if the sample size was larger. The driving histories of the CVs were unable to be assessed due to the inability to obtain this data from 3 of the 6 participants.

Strengths

A growing number of female service members, and female exposure to combat, elicits a need for research in this population. This study extends previous findings indicating that there are differences in the post-deployment health of males and females to address a gap in literature. Driving fitness and driving safety are important concerns for post-deployed CVs given increased risk for crash, and related injuries and fatalities. Since CVs are prone to an increased risk in MVC, a better understanding of factors impacting post-deployment driving can inform education and intervention efforts. Moving forward, we will examine responses to intervention to determine if there are clinically relevant differences that may be addressed in a driving intervention.

Implications for Practice

Understanding reasons for the differences between post-deployment health of males and females can encourage gender-specific approaches to therapy and/or intervention. Occupational therapists addressing CVs post-deployment needs may benefit from awareness of Veteran-centric driving fitness and community mobility concerns.

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Comparative Case-Study Analysis: Examining Driving Error Differences among Male and Female Veterans Post-deployment

I-MAP
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University of Florida
Institute for Mobility, Activity, and Participation

Background

- Since 2001, the number of combat-exposed female service members has increased.[1]
- Post-deployment, male and female Combat Veterans (CVs) often experience deployment-related medical conditions, and difficulty with community mobility and driving fitness.[2]
- Post-deployment driving differences that may impact the driving fitness, crash risk and community reintegration of RCV has not been well described in existing literature.

Study Aims

Our overall question was: For six Veterans, three males and three females, who participated in a DOD-funded driving intervention study: Are there observable differences in the errors made by males and females in the efficacy and effectiveness studies for an occupational therapy driving intervention (OT-DI)? We analyzed:

- Demographic data, co-morbidities, exposure history.
- Driving errors differences by number and type.

Method

- We analyzed data of 6 participants from two larger studies (Classen et al., 2014 and 2017),[3,4] both randomized controlled trials (RCT) of an occupational therapy-driving intervention (OT-DI) versus traffic safety education for combat veterans.
- Baseline testing included clinical tests of vision, cognition, and motor abilities; and two 6-8 minute drives on a driving simulator (DriveSafety CDS-250).
- This sub-study employed a comparative case-study design, examining differences between three pairs of CVs (each pair with one male and one female).
- We used descriptive statistics to analyze:
  - Demographic data (e.g., gender, age); comorbidities such as Traumatic Brain Injury (TBI), orthopedic issues, and Post-Traumatic Stress Disorder (PTSD); and exposure history (e.g. blast exposure).
  - Driving errors observed by number and type, i.e., speed regulation, lane maintenance, visual scanning, gap acceptance, adjustment to stimuli, vehicle positioning, signaling, and the total number of errors.

Results

- Participants included 3 males (age 34, 37, and 38) and 3 females (age 25, 33, and 39). Participants were mostly white. Female participants were more likely to have some college education.
- For co-morbidities (Figure 2), more male veterans reported TBI (3 males, 1 female) and more females veterans reported orthopedic issues (0 males, 2 females). More females reported PTSD (2 males, 3 females) and they reported a wider range of co-morbidities (e.g. diseases affecting vision).
- More females reported blast exposure for 4 of 5 categories (improvised explosive device, grenade, land mine, and sniper fire).
- For driving errors, lane maintenance was the most common driving error for males (m= 8.33, SD± 7.64) while overspeeding was the most common error for females (m= 7.00, SD± 7.00).

Figure 1. VA Mobile Driving Simulator
Left – Mounted in Dodge Sprinter Van
Right – Veteran driving the simulator

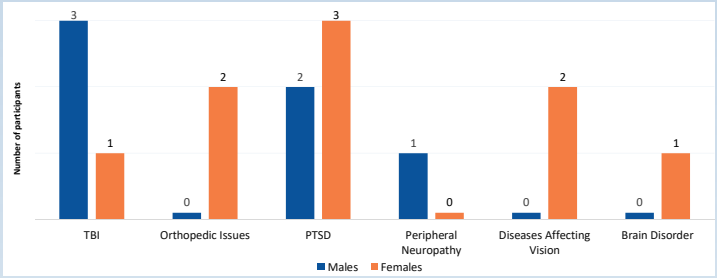

Figure 2. Co-morbidities

Error:	Visual Scanning		Lane Maintenance		Under-speeding		Over-speeding		Vehicle positioning		Adjustment to stimuli		Signaling		Gap acceptance		Total driving errors	
Gender	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Min	-	-	-	-	3	3	2	2	1	-	-	-	2	-	-	-	17	20
Max	-	3	15	5	7	11	4	15	-	3	2	2	5	3	1	1	33	32
Mean	-	1.67	8.33	2.33	4.67	6.67	2.67	7.00	2.00	5.00	1.00	1.00	3.00	1.67	0.67	0.67	27	24
Std. Dev.	-	1.53	7.64	2.52	2.08	4.04	1.15	7.00	1.00	1.67	1.00	1.00	1.73	1.53	0.58	0.58	8.72	6.92

Figure 4. Error type: minimum, maximum, mean, standard deviation
Legend: M= Male, F=Female, "-" = Zero

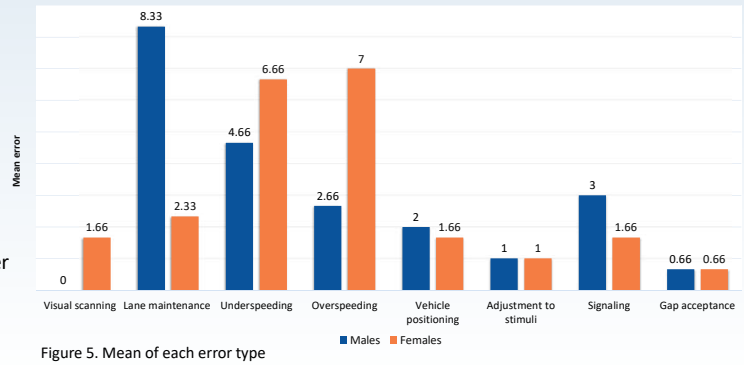

Figure 5. Mean of each error type

Discussion

- Our findings, while preliminary, illustrate differences in the demographics, co-morbidities, exposure and driving errors of three Veteran pairs.
- Despite differences in number/type of driving errors, overall results (total errors) were similar.
- The RCTs had limited female Veteran participation, contributing to a small sample size and limiting our generalizability.
- By illustrating clinically relevant differences between male and female Veterans in driving-related factors, these findings inform future research.
- As the study proceeds, we will examine response to intervention to determine if there are significant differences that may be addressed in a driving intervention.

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Acknowledgments

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- Infrastructure and support were provided by the University of Florida's Institute for Mobility, Activity, and Participation, the North Florida/South Georgia Veterans Health System, and the VA's Center of Innovation on Disability and Rehabilitation Research, Gainesville site, Florida.
- Participants came from UF I-MAP/ VA Collaborative studies funded by DOD:
  - Efficacy of a Driving Program on Safe Community Mobility for Combat Veterans (Classen et al., 2014)[3]
  - Effectiveness of a Driving Intervention on Safe Community Mobility for Returning Combat Veterans (Classen et al., 2017)[4]

UF College of Public Health & Health Professions
UNIVERSITY of FLORIDA

FOTA 2018 – DOD Interim Findings

Session Format: Professional Research Poster

Proposal Title (78/150 with spaces): Driving Intervention for Returning Combat Veterans: Interim Findings of a Randomized Control Trial

Presenter Info:

1. Sherrilene Classen, PhD, MPH, OTR/L, FAOTA, FGSA
2. Sandra Winter, PhD, OTR/L

List of presenter publications (4/4 publications)

1. Hannold E. M., Classen S., Winter S., Lanford, D. N., & Levy C. E. (2013). Exploratory pilot study of driving perceptions among OIF/OEF Veterans with mTBI and PTSD. *Journal of Rehabilitation Research & Development*, *50*(10), 1315-30.

2. Classen, S., Levy, C., Meyer, D., Bewernitz, M., Lanford, D. N., & Mann, W. C. (2011). Simulated driving performance of combat veterans with mild traumatic brain injury and posttraumatic stress disorder: A pilot study. *American Journal of Occupational Therapy*, *65*, 419-427. doi:10.5014/ajot.2011.000893

3. Classen, S., Monahan, M., Canonizado, M., & Winter, S. (2014). Utility of an occupational therapy driving intervention for a combat veteran. *American Journal of Occupational Therapy, 68*, 405–411. http://dx.doi.org/10.5014/ajot.2014.010041

4. Classen, S., Winter, S., Monahan, M., Yarney, A., Lutz, A. L., Platek, K., & Levy, C. (2016). Driving intervention for returning combat veterans: Interim analysis of a randomized controlled trial. *OTJR: Occupation, Participation and Heath, 37*(2), 62-71. doi: 10.1177/1539449216675582

Level of Material: Introductory

Abstract Synopsis: (298/300 with spaces)

Returning combat Veterans face an increased risk for motor vehicle collisions, injuries, and deaths. This poster presentation will highlight the necessary steps used in a research program while conducting a clinical trial to assess the effectiveness of an Occupational Therapy Driving Intervention.

Learning objectives: (3/3 objectives)

At the conclusion of this session:

1) Participants will comprehend the driving performance difficulties that returning combat Veterans face on civilian roads.

2) Participants will recognize the necessity of pilot and feasibility studies for conducting a driving assessment and developing an intervention with returning combat Veterans.

3) Participants will synthesize the key components of a clinical trial methodology.

References:

1. Hannold E. M., Classen S., Winter S., Lanford, D. N., & Levy C. E. (2013). Exploratory pilot study of driving perceptions among OIF/OEF Veterans with mTBI and PTSD. *Journal of Rehabilitation Research & Development*, *50*(10), 1315-30.

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FOTA poster presented November 2018

Driving Intervention for Returning Combat Veterans: Interim Analysis of a RCT

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I-MAP

Institute for Mobility, Activity, and Participation

VA | U.S. Department of Veterans Affairs
Veterans Health Administration
Center of Innovation on Disability and Rehabilitation Research

BACKGROUND

Incidence of motor vehicle crashes (MVC) among returning combat veterans (CVs) is a concern. An earlier driving study conducted on a driving simulator (CVs from OEF/OIF with PTSD and mild TBI, n=18) indicated that CVs made significantly more speeding, adjustment-to-stimuli and total errors compared to healthy controls[1]. In a follow up study, researchers studied the benefit of an occupational therapy driving intervention (OT-DI) in reducing driving errors for a single subject with post-traumatic stress disorder (PTSD) and orthopedic injuries[2]. The results indicated an overall decline in driving errors from 33 to 9 at post-intervention. The post-intervention results demonstrated a reduction ($p < .05$) in lane maintenance errors and total number of driving errors.

PURPOSE

This study determined if an OT-DI could significantly ($p < .05$) reduce driving errors (number and type) in CVs from OEF/OIF with *polytrauma*, when compared to Traffic Safety Education (TSE) in a randomized control trial.

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 and the Department of Defense Human Research Protection Office (HRPO).

Design: This study used an unblinded parallel arm randomized controlled design with random allocation of study participants to control and intervention groups.

Participants: CVs were recruited from North Florida/South Georgia Veterans Health System. A total of 26 participants completed both baseline and post-test 1 assessments. *Inclusion criteria* - OIF/OEF CVs diagnosed with polytrauma (e.g., combination of two or more combat-related conditions such as TBI/ orthopedic injury, and PTSD), who drove prior to condition onset; have a valid driver's license or are eligible for a driver's license; are community dwelling; scored no less than 24/30 on the Mini-Mental State Examination (MMSE); reported driving difficulty. *Exclusion criteria:* CVs with severe psychiatric (e.g., psychoses) or physical conditions (e.g., multiple amputee) that limit their ability to drive; have been advised not to drive by physician due to effects of medications such as psychotropics; have severe, irremediable medical conditions (e.g., severe TBI) as per the consulting physician; pregnant females or those planning pregnancy; and VA employees.

Procedure: At baseline participants completed consent forms, Institute of Mobility Activity & Participation's (I-MAP's) clinical battery of tests[1,2,3] and driving assessment in a simulator with established reliability among the three raters [4]. The intervention group received Occupational Therapy Driving Intervention (OT-DI), consisting of three x 1 hour sessions (Session 1: Driving evaluator reviewed explicit driving errors with CV; Session 2: Driving evaluator provided tailored strategies to mitigate errors; Session 3: CV drove simulator with targeted feedback from driving evaluator). The control group received, from a driving safety professional, three x 1 hour general safety sessions (Session 1: General traffic safety discussion; Session 2: Rules of the road and knowledge of the road discussion; Session 3: drove the simulator without any feedback from traffic safety professional). Immediately after session 3 (same day, or a day or two after) Post-test 1 will occurred using the same standardized protocols.

Measures: Demographic questionnaires, Fitness-to-Drive Screening measure, cognitive, visual and motor function tests, which are not further discussed. Driving errors assessed via a standardized score sheets on the DriveSafety CDS-250 simulator (Figure 1) engineered into a Dodge Sprinter van (Figure 2).[2]

Data collection and analysis: SPSS Statistics Version 22 (IBM Corp., Armonk, NY) was used to analyze the data. Descriptive statistics was used to summarize data. Non-parametric Wilcoxon rank-sum test was used to report the group (OT-DI and TSE) difference between type and number of driving errors at baseline and post test 1.

Figure 1. Dodge Sprinter van with the CDS-250

Figure 2. VA Mobile DriveSafety CDS-250 Driving Simulator

RESULTS

Table 1
Demographics statistics for the returning combat veterans (N=26) by Intervention (n=13) and Control (n=13) groups.
Legend: M: Mean, SD: Standard deviation

Demographics	Intervention group Freq.(%) or *M (SD)*	Control group Freq.(%) or *M (SD)*
Age	38.69 (±6.52)	37.31 (±10.21)
Gender		
Male	13 (100.0%)	13 (100.0%)
Race		
White	13 (100.0%)	8 (61.5%)
Other	0	5 (38.5%)
Ethnicity		
Hispanic or Latino	2 (15.4%)	2 (15.4%)
Not Hispanic	11 (84.6%)	11 (84.6%)
Educational Level		
Completed High school and lower	2 (15.4%)	2 (15.4%)
Greater than High school	11 (84.6%)	11 (84.6%)
Marital Status		
Married	10 (76.9%)	8 (61.5%)
Others	3 (23.1%)	5 (38.5%)

Table 2
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.
Legend: M: Mean, SD: Standard deviation'

Driving error type	Intervention group		Control group	
	Baseline	Post-test 1	Baseline	Post-test 1
	M (SD)	*M (SD)*	*M (SD)*	*M (SD)*
Speeding	12.31 (7.40)	4.92 (4.09)	13.00 (7.81)	10.08 (7.30)
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 3
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.

Legend:
A1: Control baseline vs. Control post test 1
A2: Intervention baseline vs. Intervention post test 1
A3: Control baseline vs. Intervention baseline
A4: Control post test 1 vs. Intervention post test 1
Legend
M=mean, SD=standard deviation

Analysis	Test statistic	Visual scanning	Lane maintenance	Speeding	Vehicle positioning	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
	M (SD)	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)
	p-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
	M (SD)	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)
	p-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
	M (SD)	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)
	p-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
	M (SD)	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)
	p-value	.48	.26	.05	.31	.05	< .001	.02	.01

Figure 3. Driving error trendline: Comparison between Control baseline vs. Control post–test 1

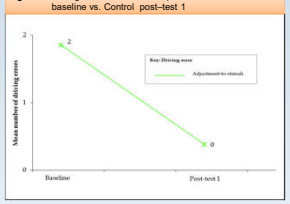


Figure 4. Driving error trendline: Comparison between Intervention baseline vs. Intervention post–test *1*

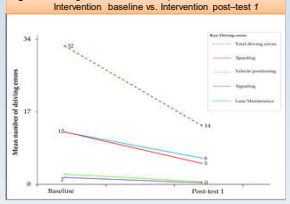


Figure 5. Driving error trendline: Comparison between Control post-test 1 vs. Intervention post–test 1

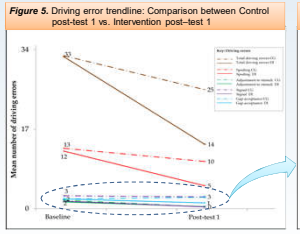
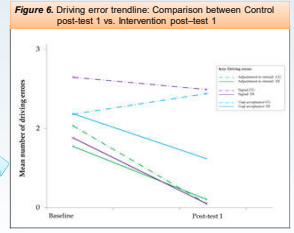


Figure 6. Driving error trendline: Comparison between Control post-test 1 vs. Intervention post–test 1



DISCUSSION

Participants in this study had medical conditions including mTBI, PTSD and/ or orthopedic conditions, and reported driving difficulty. Our findings (Table 2) indicated a decrease in mean driving errors between baseline and post-test 1, suggesting that the intervention group benefited from the OT-DI whilst the control group benefited from the TSE sessions. Interestingly at baseline, both groups had similar driving errors. However, at post-test we measured a significant reduction in number of driving errors for the intervention group. Generally, between the baseline and post-test 1 tests, the intervention group demonstrated error reductions in speeding, signaling, adjustment-to-stimuli, gap acceptance and total driving errors.

Limitations: Limitations included 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. The use of video to deliver the TSE 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 control and intervention groups because the driving scenarios used at baseline and post-tests were the same, and the presence of scripted events was not randomized. Timing for post test 1 was different for both groups, and the delay for control group testing could have significantly affected findings. Lastly, sample size (N=26) for this study was small, hence caution should be exercised in interpretation.

Strengths: This study followed a blocked randomization scheme to allocate participant to control and intervention groups. At baseline, group participants were not significantly different in demographics, exposures, clinical tests, and driving errors. In addition to analysing intervention efficacy, our study design allowed us to establish the feasibility of this multi-site intervention.

Practice Implications: This study illustrates early empirical support for our simulator-based occupational therapy driving intervention, focusing on veterans' driving fitness. Beyond crash risk, driving difficulty of CVs impacts their ability to fully engage in everyday life. As such, development of an evidence-informed driving simulator protocol is critical and will facilitate the ability of occupational therapists inside and outside of Veterans Affairs and military settings to evaluate and treat fitness to drive deficits in this CV population.

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Appendix C

CONSORT Diagram for Subjects: Effectiveness study – 05.14.2019