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14. ABSTRACT

The proposed project aimed to develop and test a method for enhancing emotion regulation and reducing operator-related risk during civilian driving in OEF/OIF returnees with driving-related distress. Execution involved three main components. The first was the development of a system for objectively measuring on-road driving behavior and concurrent autonomic and visual attentional control. The second was the development of a cognitive-behavioral intervention combining breathing retraining and cognitive reappraisal. The third was the execution of a formative trial with Veterans complaining of driving related distress. As a guarantee of disseminability, all components needed to compatible with on-road driving assessments currently performed by driving rehabilitation specialists at VA Palo Alto Health Care System. A portable, low-cost, user-friendly driving measurement system was developed in collaboration with Fujitsu Laboratories of America who provided substantial engineering assistance *gratis*. A preliminary intervention designed to reduce autonomic arousal during driving was found to achieve the expected effects on autonomic arousal in the car. The trial was executed with partial success, participant recruitment proving to be more difficult than anticipated based on prior contacts with recruitment sources. A proposal (LOI) has been submitted to extend this work to Veterans with TBI. A proposal is planned to develop a mobile-app-based tele-heath version of the approach intended to overcome barriers to research recruitment, and later, treatment delivery, such as limited time and rurality.

15. SUBJECT TERMS
driving, post-traumatic stress, autonomic arousal, visual attention , steering precision,

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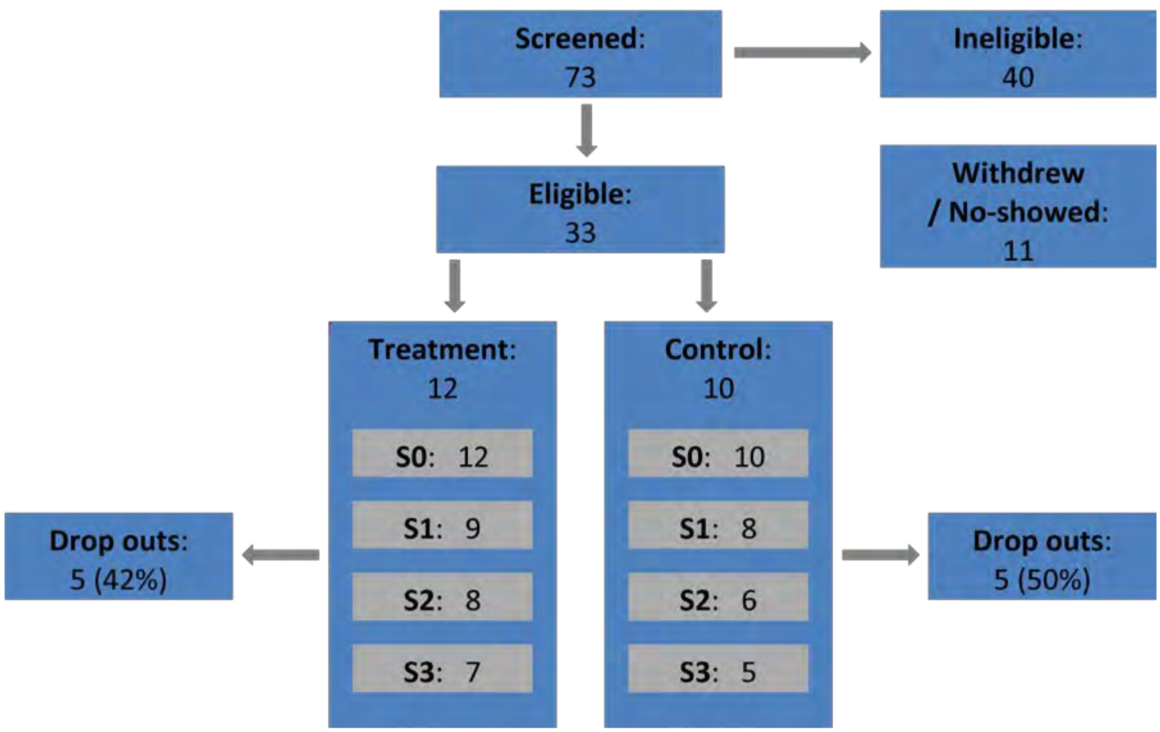
INTRODUCTION

The proposed project aimed to develop and test an intensive rehabilitative technology aimed at enhancing emotion regulation and reducing operator-related risk during civilian driving in OEF/OIF returnees burdened by severe driving-related distress and disability. This in-car technology was to have two main components. The first was a system for measuring driving behavior, visual attention, and autonomic arousal during on-road driving. The second was a cognitive-behavioral intervention combining breathing retraining/heart rate variability biofeedback and cognitive reappraisal. Both components were to be compatible with on-road driving assessments currently performed by certified driving rehabilitation specialists (CDRS) at the VA Palo Alto Health Care System (VAPAHCS) on neurologically intact patients and those with mild-to-moderate non-focal traumatic brain injury. A four-session intervention (one in office, three on-road) was designed with random assignment to one of two groups receiving different intensities of intervention during driving pauses after exposure to on-road trauma reminders. The "experimental" group engaged in individualized cognitive reappraisal and a paced breathing exercise. The "control" group listened to music. Participant flow is summarized in Figure 1 below.

Figure 1



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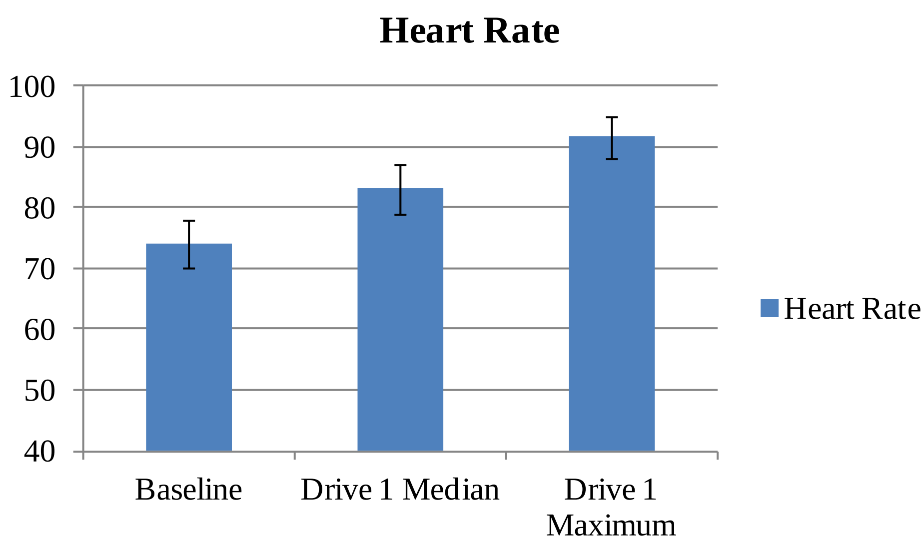
KEY RESEARCH ACCOMPLISHMENTS:

Preliminary Confirmation of Excessive Autonomic Arousal During Driving in Veterans with Driving Distress

Perhaps the most important observational finding of this study was that the Veterans who engaged in treatment manifested substantial autonomic activation during driving. Figure 2, below, plots median heart rate during the laboratory (Baseline) session, median heart rate during Drive 1, and one-minute maximum heart rate during Drive 1. Across participants, the average maximum heart rate during a supervised drive under suburban conditions was ~ 18 BPM higher than heart rate in the laboratory. These excursions are comparable to those observed in healthy persons engaged in a serial subtraction challenges (Kelsey, et al., 1999). They are approximately four times those observed in Veterans with PTSD engaged in a serial subtractions (Orr, Meyerhoff, Edwards, & Pitman, 1998), and two to seven times those induced in Vietnam Veterans by trauma reminders in the laboratory (Blanchard, Kolb, Pallmeyer, & Gerardi, 1982; Keane, et al., 1998). Because these are one-minute values they cannot be accounted for by transient physical manoeuvers such as hard braking.

Figure 2



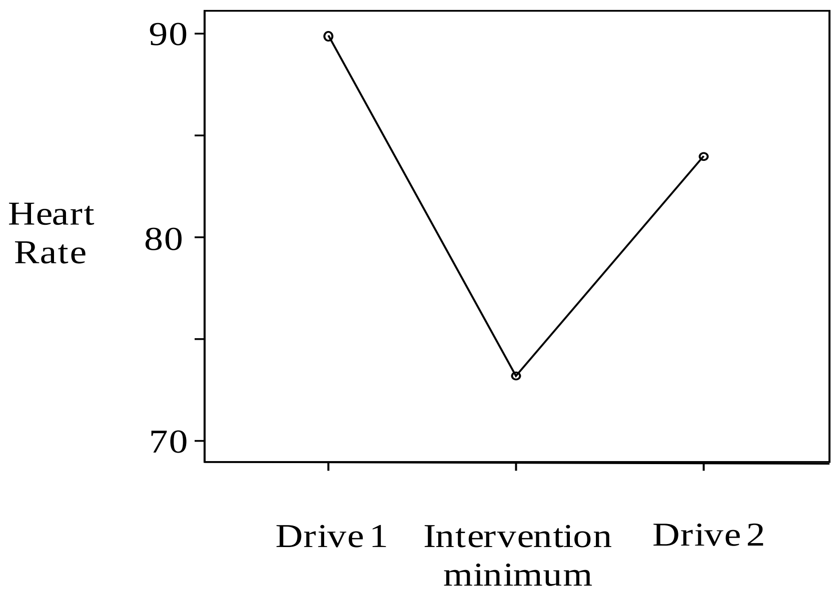
Preliminary Confirmation that a Brief Intentional Driving Pause Can Mitigate Excessive Autonomic Arousal during Driving in Veterans with Driving Distress

As plotted in Figure 3, large reductions in heart rate were observed when participants pulled off the road with the explicit instruction to reduce their distress either by engaging in the active treatment of cognitive reappraisal plus breathing retraining or by engaging in the control intervention, listening to music. We did *not* obtain evidence that the experimental treatment was more efficacious than the active control; however, drop out was higher in the control group. Heart rates were lower in session two than in session one suggesting a cummulative treatment effect. Effects on steering precision, accelerator pedal movement, and vehicle accelerations are being analyzed.

A Smartphone-Based On Road Driving Measurement System

This study involved the continuous quantification of heart rate, gaze, vehicle accelerations, and steering wheel and accelerator pedal motions during on-road driving. In addition, heart rate (HR) was to be continuously monitored as a safety measure, and respiratory sinus arrhythmia (RSA) calculated in real-time and supplied as a feedback signal during breathing retraining. The first version of this system involved three separate data acquisition programs running concurrently on a high-end laptop. The programs from three different vendors employed divergent interfaces and resulted in multiple data files with variable naming and storage conventions. The resulting data requiring substantial post-processing to achieve even an initial data quality review. Serendipitously, during the first year of funding, we were contacted by representatives from Fujitsu Laboratories of America (FLA) who were seeking a beta site for an iPhone-based approach to real-time data integration across multiple sensors. The kernel of this system is the "Sprout", a miniaturized computer employing the Samsung ARM 11 processor and running on

Figure 3



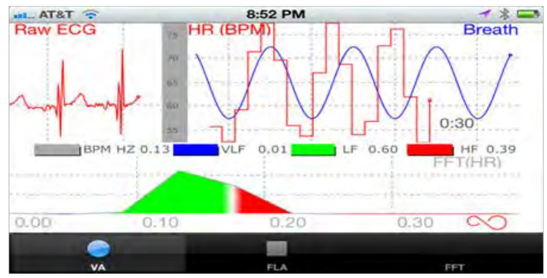
Linux. The Sprout hosts a number of connectivity protocols including Bluetooth, 802.11b/g, and USB, a web-server, and a flexible data acquisition system that can manage multiple data streams with different sampling rates and both equal and variable interval sampling. In addition, the Sprout can be programmed to perform real-time processing such as filtering, R-wave detection, and RSA spectral processing. Results can be streamed back to the iPhone for visualization in near-real-time.

With *gratis* support from FLA, we ultimately replaced our original system with an iPhone-based system which eliminated the laptop and replaced the wireless accelerometers with an iPhone 4s and three iPod Touches running light applications to stream accelerometer outputs to the Sprout. Key features of this system are summarized in Figure 4. FLA built an interface to the wireless Zephyr Technologies BioHarness system that transduces ECG, respiration and activity (and is available on GSA contract). FLA also produced an iOS application that monitored connectivity with the BioHarness and iPods and relayed their data to the Sprout. While doing so, this same app provided near-real-time HR and RSA display adequate for biofeedback. GPS information was harvested from the iPhone and relayed to the Sprout so that all data were geotagged. Finally, a second iOS app collected behavioral observations using an efficient pushbutton interface. These observations were then streamed to the Sprout and synchronized with the continuous data. After each testing session, synchronized and merged data were downloaded wirelessly from the Sprout to a laptop in the form of two files, one containing ECG and sampled at 256 Hz, and one containing all other data nominally sampled at 20 Hz. A sample output plot is presented in Figure 5, below. The iPhone/Sprout-based system represented a major advance in disseminability relative to our original system. In addition to converting the hardware component to a set of smaller, lighter and more user-friendly devices, it produced pre-merged data, and added important new features such as mapping and time-stamped behavioral observations. Key features of the system are displayed below.

Figure 4

Fujitsu Sprout

Breathing Training Feedback Display



Flame App for Behavioral Observations

Safety

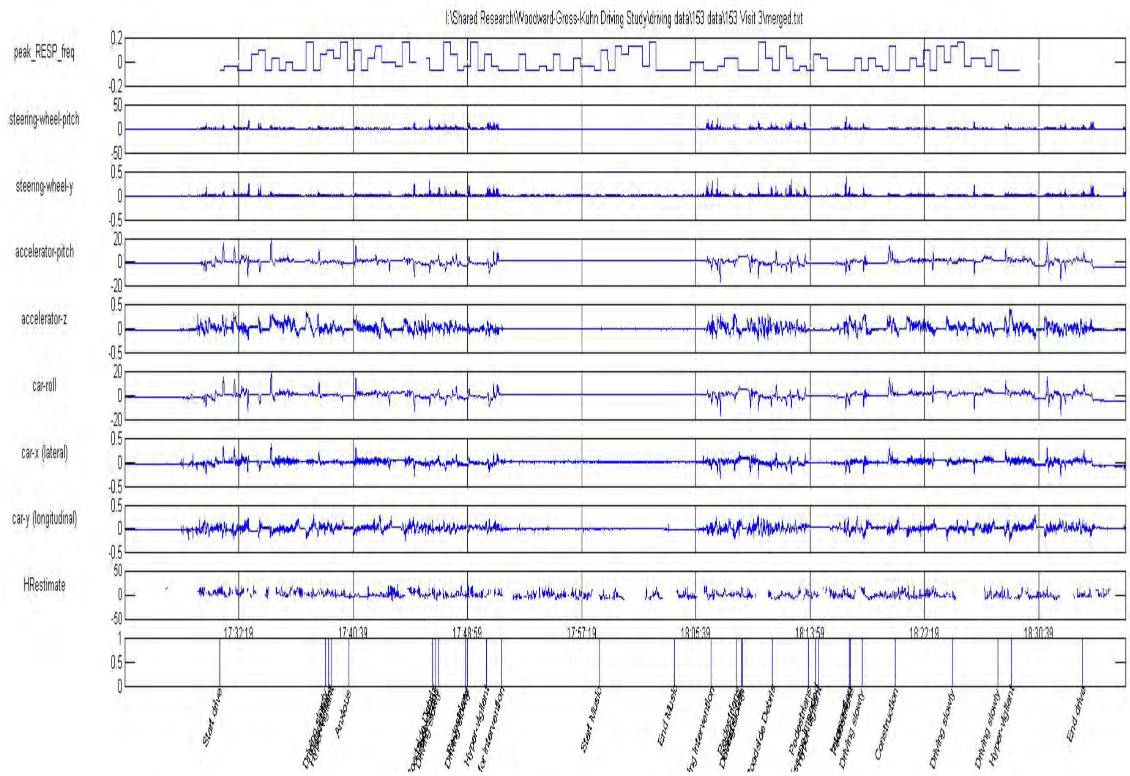
The overwhelmingly positive safety record of Department of Veterans Affairs driving rehabilitation was reconfirmed in this study.

Quantification of Visual Attention during Driving

Based upon anecdotal reports, we were concerned that Veterans with combat driving trauma allocated excessive attention to features of the civilian driving environment reminding them of threats in the operational environment. These features included objects on the side of the road, people on the sidewalks speaking into mobile phones, people appearing to watch traffic, etc.

Redirection of the Veteran's attention away from sources of current driving risk such as the car immediately in front, impending road access points, etc would presumably increase the risk of

Figure 5



accidents, a possibility supported by data from USAA, insurer of many Veterans and active duty. (https://www.usaa.com/inet/ent_blogs/Blogs?action=blogpost&blogkey=newsroom&postkey=returning_troops_find_new_dangers&akredirect=true). We proposed to measure visual attention during driving using an advanced eye-movement and gaze quantification system (faceLAB, Seeing Machines), obtained with non-grant funds. This system could be integrated into the DriveSafety simulator used at VAPAHCS and has since performed well in that environment. Importantly, faceLAB relies on stereo video cameras to image the eyes and face rather than specialized glasses worn by the participant. Hence, the participant's head is unencumbered by wiring during driving, reducing burden and enhancing safety. Though substantial effort went in to instituting faceLAB-based gaze quantification during driving, reliable measurements were achieved only when drivers did not wear sunglasses. As this study took place in central California, most sessions were conducted under conditions of full sun in which participants preferred to wear sunglasses. As a result, this feature of the methodology was reluctantly dropped. (Though Seeing Machines and similar companies have targeted the quantification visual function during driving, the commercially-relevant parameter is lid closure indexing drowsiness, a much easier measure to acquire.) The later phase of the study saw the advent of commercial point-of-view (POV) video cameras that integrated with the Apple iOS environment upon which our measurement system came to be based. We have piloted this low cost approach to gaze estimation using the Looxcie technology (Looxcie 2, $149). This 3 oz. camera clips to the ear or to a hat brim and provides a continuous video record of the user's line-of-sight that is time-stamped according to the iPhone clock. Storage is local and connection to the iPhone wireless so that video can be monitored and stored without encumbering the driver with wiring. Gaze direction can be estimated qualitatively and quantitation should achievable with more advanced image processing than we could within the scope of this project. A major advantage of this approach is the capture of gaze *content* allowing the correlation of large heart rate accelerations with the subject's visual experience for later review by the clinician. The privacy issues currently under public discussion in relation to other POV video recording systems such as Google Glass are not pertinent here as the video record is dominated by the driving field of view and uninvolved persons are imaged only at a distance.

Example of Looxcie-Based POV Video

Caveats

Recruitment

Pre-application contacts with VAPAHCS clinicians in primary care and mental health settings provided strong indications that a robust referral base was available to this study. Clinicians confirmed that many of their patients reported driving distress and indicated enthusiasm for the study and the prospects of referring patients to it. Unfortunately, actual recruiting did not reflect these pre-study indications and remained problematic throughout the course of the study. Our efforts to address this problem took two tracks, one aimed at loosening the inclusion/exclusion criteria initially imposed by the IRB, and a second aimed at broadening outreach. Multiple incremental protocol revisions eventually removed criteria related to PTSD and depressive symptomology, the regularity of driving, the identity of the official automobile owner and insured, the recency of moving violations and/or motor vehicle accidents, and the restriction to OEF/OIF Veterans. (Most of these criteria had been imposed as part of negotiations with the IRB in order to preserve the study's mandated expedited status.) Loosening screening criteria reduced the number of screen-outs; and in no case did our experience suggest that any be re-imposed (See Safety below). Our efforts to broaden outreach to potential participants took a number of forms. In addition to comprehensive hospital flyering, and messaging to appropriate primary care treatment teams, outreach was directed to Veterans service organizations and local community colleges with large OEF/OIF Veteran enrollments (De Anza College, San Jose State, Canada College). These are commuter schools within easy reach of the Palo Alto Division of the VAPAHCS. The De Anza student body, for instance, includes ~500 self-identified OEF/OIF Veterans. The PI and study coordinator met with the De Anza counseling faculty on two occasions. The PI made personal visits to the De Anza OEF/OIF student organization meetings. To our surprise, those meetings, and similar meetings at San Jose State, were attended by fewer than 10 young Veterans. While attendees endorsed varying levels of driving distress, and took our flyers, they did not contact us in order to participate. Additional outreach strategies included hiring a flyering service that targeted regional centers and shopping malls, the placement of craigslist ad, and posting a booth at a Marine Stand-Down. A Facebook ad was viewed approximately 400 times without a “conversion.” Low recruitment was compounded by no-shows. Approximately 80% of all scheduled sessions during the last three months of operation were no-shows. While systematic data bearing on poor recruitment and no-shows were not obtained, the most commonly-voiced explanation was conflict with employment-related activities or job search. These anecdotal reports were consistent with the poor economic conditions in the SF Bay Area. While research recruitment of OEF/OIF Veterans is recognized to be difficult at VAPAHCS as at many VA sites, the demands of this study were limited - four sessions and a phone call - all compensated. Our difficulty recruiting for this trial despite the reported prevalence of driving-related complaints has led us to consider an alternative mode of packaging an intervention designed to reduce deployment-related driving risk (See Future Directions).

Formal On-Road Session Plan

The session plan developed for the trial was a test-intervene-test format. Road conditions distressing to participants were identified during the baseline session. These were sent to the collaborating Certified Driving Rehabilitation Specialist (CDRS) who had extensive knowledge of local roads. The CDRS would then plan routes that included the identified conditions. The aim was to have participants drive these routes twice, once before, and once after the experimental or control intervention, enabling pre- and post- measurements. It was our experience that the session driving plan was often subverted by unexpected road conditions and events (e.g. being cut off by another driver) that effectively inserted unrepeatable trigger phenomena into drives. While we continue to believe that an on-road intervention poses many advantages from the standpoint of learning theory, controlled session plans cannot be systematically executed as in a driving simulator.

Measurement of Heart Rate during Driving

Three different approaches to heart rate measurement during driving were tested during this development trial. The first involved the use of standard foam-backed ECG electrodes wired to a battery-power physiological amplifier connected to a laptop. This system provided excellent signal quality and monitoring capability; however, it tethered the driver to the equipment which was clearly not ideal from the perspective of maximizing safety and minimizing burden. The iPhone-based system developed in collaboration with FLA was designed to interface with the Zephyr BioHarness. This system utilizes a chest strap and silverized cloth electrodes. It transmits ECG, HR, respiration and activity data wirelessly (over Bluetooth) to an iPhone on which data quality can be monitored in near-real time. The system is sold under GSA contract and is used successfully in many training contexts with fit users. Unfortunately, it was our experience that the Zephyr system did not reliably record high-quality ECG in participants who had acquired substantial upper body fat since discharge from the military. As a backup, we also collected ECG using the Actiwave system, which uses two standard ECG electrodes and houses miniaturized amplification, battery, and memory storage on one of the electrode connectors. This system also exhibited drawbacks as the weight of the instrumented connector tended to pull the underlying electrode off the chest, and data loss could not be monitored in real time and corrected. Near the end of our funding period we learned of a new iPhone and Android-compatible ambulatory ECG system which has undergone testing in extreme driving conditions. Moreover, the Vital Connect system, as currently supplied, can be adapted to provide all of the physiological and accelerometric sensing and streaming provided by our current system.

REPORTABLE OUTCOMES:

Woodward, S.H., Kuhn, E. Gross, J.J., Samuels, M., Bertram, F. In-car intervention for post-deployment driving distress: A developmental trial. International Society for Traumatic Stress Studies, Los Angeles, CA. November, 2012.

Woodward, S.H., Kuhn, E. Gross, J.J., Samuels, M., Haile, A., Bertram, F., Lebus, R. In-car intervention for post-deployment driving distress: A developmental trial. Manuscript in preparation.

CONCLUSIONS:

Our attempt to develop an intervention to address deployment-related driving distress and elevated driving risk using a conventional treatment delivery format employing an expert provider based in a hospital encountered a number of obstacles. First and foremost, only small numbers of Veterans could be induced to take advantage of the program's availability despite extensive local advertising, numerous personal contacts with potential participants, and substantial media interest. At the same time, this study has confirmed that some and perhaps many Veterans with post-deployment driving distress are contending with substantially elevated autonomic arousal while driving civilian roads, a finding compatible with their own reports of inappropriate, risk-elevating driving behavior (Kuhn, Drescher, Ruzek, & Rosen, 2010). This autonomic activation was strongly attenuated by a brief "stand down" in a safe parking area whether that involved the active intervention of cognitive reappraisal plus paced breathing or simply listening to preferred music.

Future Directions

The above findings combined with new developments in mobile technology suggest an alternative intervention modeled on an approach to driving risk reduction increasingly used by the auto insurance industry. That approach places a device in the vehicle which passively tracks a small set of driving behaviors (times of drives, amount of driving, episodes of hard braking), uploads that data to the insurer via a cellular telephone network, and rewards objectively low-risk driving with insurance premium reductions (http://www.progressive.com/auto/snapshot/). This model could be replicated and enhanced using an iPhone or Android phone running an app similar to the one developed in collaboration with FLA through this study. Providing a superset of Snapshot functions, the app would integrate richer vehicle acceleration information, GPS-based speed, and heart rate as supplied by a wireless ECG sensor such as the Zephyr BioHarness or the Vital Connect device. The app would upload all data to a HIPAA-compliant cloud-based storage facility. (The Vital Connect system already does so.) Whenever vehicle speed, accelerations, and/or heart rate exceeded collaboratively-developed thresholds the app would emit an audible alarm. Users would be financially incentivized for responding to these alarms by pausing their drive within a preset period of time and reducing autonomic arousal below a collaboratively-developed level. Thus, users would be repeatedly rewarded for moderating their driving behavior and for down regulating their autonomic activation using a personalized method. To prevent gaming of the system, users would be penalized for failing to respond to alarms. Adherence could be easily monitored by reference to uploaded data. Earned incentives could seamlessly accrue to an online account at one of a number of national vendors. Crucially, the intervention could be disseminated to personnel immediately on return from deployment and to any geographical location conditional only on the user's possession of a smartphone. Psychoeducational materials now under development by Dr. Kuhn, a co-investigator on this study, could be delivered via the same app while interactions with a remote treatment manager could employ encrypted voice or video calls as some tele-mental health programs already do. Users could self-administer the intervention at their convenience and for as long as necessary as a function of their level of driving distress and desire for financial incentives, with an extra incentive stream associated with use of the more burdensome heart rate collection device. Importantly, the system would be fully applicable to motorcycle users. Per unit costs would be low and scale-independent. The PI is now exploring potential funding sources for and collaborators in the development of such an app. The

National Center for PTSD, Dissemination and Training Division, is the DVA's lead site for the development of mental health-promoting mobile applications, and has collaborated with the Defense Center of Excellence, National Center for Telehealth and Technology (T2) to deliver PTSD Coach, CBT-I Coach, and Stay Quit Coach.

The PI is also developing, in collaboration with Drs. Maheen Adamson, Acting Director of Research, War Related Illness & Injury Center (WRIISC), VA Palo Alto, CA, and Stephanie Hayner, Director of Rehabilitation Research, Santa Clara Valley Medical Center, a second proposal incorporating the in-car measurement technology developed in collaboration with FLA. Briefly, the proposal seeks to develop a low-cost driving assessment methodology applicable to the driving impairments associated with mild-to-moderate traumatic brain injury (mTBI) variably compounded by PTSD. This assessment approach would target vehicle control, sustained attention, and memory functions necessary for safe driving. It would rely solely on a laptop equipped with a steering wheel peripheral. The system could be easily transported or shipped to rural sites currently un-served by driving rehabilitation. The laptop-based driving assessment would be based on scanner-compatible tasks, allowing an examination of neuroimaging correlates of impaired versus preserved driving function in mTBI. The validity of the laptop-based driving assessment would be validated against both a closely-matched simulator-based version and against on-road driving.

A possible source of referrals to a deployment driving risk reduction intervention is the Traffic Courts. Innovative Veterans' Courts have been initiated at the superior court level in Buffalo, NY, Santa Clara County, CA, and elsewhere. The VA has partnered with these efforts by setting up the VA Justice Program. The goal of these partnerships is implement treatment-aware sentencing and to foster coordination between local justice officials and VA-based mental health providers. We are also aware of a new effort in Los Angeles, CA (home to the second largest population of OEF/OIF returnees after San Diego) to extend this model to the Traffic Courts where most driving-related cases are adjudicated. Our team has opened discussions with the national staff of the VA Justice Programs (sited in Palo Alto) who plan to bring the issue up with the local jurist conducting a Veteran’s court (Judge Stephen Manley). It would be highly consistent with this model to direct justice-involved Veterans to an appropriately tailored driving intervention. A second potential benefit of alternative sentencing would be to reduce the likelihood that police officers apprehending deployment-influenced drivers would fail to cite for fear of involving them in a legal system insensitive to the impact of combat driving training and experience. Such failures to cite have had grave consequences.

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APPENDICES:

None

LIST OF PERSONNEL RECEIVING PAY FROM THE STUDY:

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