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14. ABSTRACT The project is currently undergoing review by the human subjects review at the Walter Reed Army Medical Center and the Army (USAMRMC ORP HRPO). The materials were submitted to the Walter Reed committee in June, 2009, and we have responded to their comments. Dr. Stephenson is assisting us in preparing documents of the Army review committees. The Westat IRB has reviewed and approved the activities of the Westat team. In the meantime, the research team has had several opportunities to present the project in a variety of settings and have been provided opportunities to further develop the theory behind the concept of using service dogs to reduce the symptoms of PTSD among returning soldiers with severe cases of the disability.

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INTRODUCTION

The proposed project will study the effectiveness of service dogs in the reduction of PTSD symptoms among soldiers returning to the Walter Reed Army Medical Center (WRAMC) from Iraq and Afghanistan. The Psychiatric Service Dog Society (PSDS) has been developing the concept of using service dogs with a variety of mental health disabilities, including PTSD for the past 13 years. In a 2005 survey of Psychiatric Service Dog (PSD) handlers, 82% of the respondents with PTSD who are using a PSD reported a decline in symptom manifestation. That finding among others and the strong interest of veterans and returning soldiers, the PSD launched a listserv community for veterans of all wars who are interested in using a service dog to help reduce refractory symptoms of PTSD. The community grows on a continuing basis and after 1 year has grown beyond 150 subscribers who are actually using service dogs.

The funded research project will be the first direct test of the effectiveness of service dogs for returning warriors who are suffering from PTSD. It is a “seedling” study that will engage only 20 soldiers. They will be randomly assigned to two groups one receiving the service dog and training to handle it and the second will not receive such support until the end of the project. The measures will include behavioral assessments of general mental health and PTSD symptom manifestations as well as the biological markers that are associated with anxiety, stress and depression. The parallel measures will strengthen the study and add power to the analyses. Once the data collection is complete, and if the findings are positive, there will be a need for a larger study examining the effects of PSDs on PTSD. The study is being administered and data collected by an independent party, the lead agency, Westat.

HUMAN SUBJECTS REVIEW ACTIVITIES

Dr. Bouterie, with extensive support from Drs. Love and Esnayra, has worked with the WRAMC human subjects review committee to ensure an efficient review of our protocol. She submitted the completed document on June 1, 2009 and received comments and questions in August, 2009, to which we responded. We are awaiting a final response.

Dr. Stephenson, who is the TATRIC staff member who is assisting us in preparing

the USAMRMC ORP HRPO review has provided feedback on our protocol in preparation for the second level of review. We have been working on those changes and plan to submit the document in the next quarter, once we receive a positive review from the WRAMC human subjects committee.

PRESENTATIONS AND PUBLICITY

In the meantime, the research team has had the opportunity to present the research project in several venues. The ensuing discussions have helped strengthen the development of the theoretical understanding of the way service dogs assist returning soldiers with PTSD. The veterans' listserv has provided extensive insight in ways that the dog assists persons with PTSD (See Appendix). However, the theory behind the process has grown with the presentations at several different meetings over the year (See Appendix for sample abstracts). It appears that the service dog provides assistance that is understood by the dog's handler. That is, the assistance is a construction in the mind of the handler, based on the dog's responses to the handler's behavior and the handler's understanding of his/her disability. This calls for a clear collaboration among the trainer, the treatment provider, the client and an expert on service dog functions.

Some design issues were raised in the February 2009 CRMRP meeting that addressed the small number of subjects. Because of the required costs of establishing the intervention, the budget allowed only 20 subjects. Some of the CDRMP leaders suggested that the study be doubled in size to allow for a larger sample size and increase the power. We are very interested in such an opportunity and are looking forward to the possibility. However, we believe that the design will allow us to develop an effect size that can be used in future larger studies. The matching component in the randomization procedure, multiple data points and multi-method measurements will all contribute to a more stable variance and enhance the likelihood of a reasonable effect size.

Presentations:

1. November 2008 NIH Symposium : Understanding the Human-Animal bond, Bethesda, Md.
2. February 2009 CDMRP grantee meeting, Ft. Detrick, Md.
3. May 2009 SAMHSA meeting on alternative mental health Interventions, Rockville, Md.
4. August 2009 Waltham Foundation, Leicester England
5. September 2009 Military Health Research Forum, Kansas City, Mo.

Publicity:

The project was selected by CDMRP to be one of four project featured at the Military Health Research Forum in Kansas City in September 2009. The result includes several interviews with Dr. Love and Esnayra by radio and television groups across the country. The result was over 400 news outlets with one version or another of the interviews and feature stories that were developed in Kansas City.

STAFFING ADJUSTMENTS

The key project staff have not changed; Dr. Bouterie (WRAMC PI), Dr. Love (Project PI) and Dr. Esnayra (Project Co-PI) are all very much involved. We recently had to change the dog trainer because we were unable to complete the negotiations for the Natures Way K-9 training group. As a result, we have established a relationship with the Washington Humane Society , a group who has a kennel facility across the street from the Walter Reed facility and who already has a relationship with the WRAMC in their “Dog Tag” program. Also, Dr. Magra, the Psychiatric Resident, has been reassigned and a new Resident, Dr. Soumoff , will replace Dr. Magra. These changes will be presented to the Project Officer for review and approval in the next quarter.

Appendix 1

Service Dog Functions for Persons With PTSD

PSD Assistance for persons with PTSD

Symptom(s): assistive behaviors	assistance classification
reclusiveness: canine accompanies veteran outside the home	physical task
night terrors: dog wakes veteran (optional: turn on light)	physical task
startle reaction: canine-defined personal space perimeter	physical task
forgetfulness: canine medication reminder	physical task
dissociative fugue: 'take me home' command	physical task
hypervigilance: search a room for the presence of humans	physical task
neurochemical imbalance: Team walks to stimulate endorphin production	physical task
dissociative flashback: tactile stimulation mediates sensory re-integration and orientation to time/place	physical task
alert to presence of others (i.e., 'pop a corner' or 'watch my back')	work--leveraging a dog's natural senses
dissociative spell: canine interrupts	work--mind/body
emotional regulation: canine as therapeutic distraction	work--mind/body
sensory overload: canine as alternate focus	work--mind/body
social withdrawal: canine-facilitated interpersonal interaction	work--community integration
canine alert to emotional escalation	work-- leveraging a dog's natural senses (CBT)
hypervigilance: canine environmental threat assessment	work--leveraging a dog's natural senses (CBT)
hallucinations: canine-facilitated reality testing	work--leveraging a dog's natural senses (CBT)
suicidal ideation: 'suicide prevention dog'	work—(CBT)

Appendix 2

ABSTRACT

Waltham Foundation Meeting

Leicester, England

August 2009

The Psychiatric Service Dog (PSD) Therapeutic Model: Harnessing Twelve Years of Grass-Roots Development

By Joan Esnayra, Ph.D. & Craig Love, Ph.D.

The PSD Therapeutic Model is a framework that was developed by Dr. Esnayra beginning in 1997 with significant input over time from the PSD handler community. The framework embraces an ethical approach to animal guardianship and 24/7 human-canine partnership. Persons living with mental health disabilities are choosing to train a PSD for themselves using guidelines set forth by the Psychiatric Service Dog Society (PSDS) and under the tutelage of a local professional dog trainer. PSDS has identified numerous tasks and therapeutic functions across a range of DSM-IV diagnoses that PSD may be trained to perform or provide. A majority of PSD handlers are reporting diminishment of refractory symptoms and reduced usage of psychotropic medication since partnering with their PSD. A large fraction of these come from trauma backgrounds that derive from abusive childhoods. A new trauma cohort has emerged recently among returning soldiers from Iraq and Afghanistan. PSDS and its research collaborators are currently awaiting IRB approval from the U.S. Army for a research protocol that will be implemented at Walter Reed Army Medical Center in Washington, DC. Study specifics will be discussed as part of our presentation at the Waltham Foundation.

APPENDIX 3

ABSTRACT

**PAPER PRESENTED AT THE MILITARY
HEALTH RESEARCH FORUM**

KANSAS CITY, MO

SEPTEMBER 2009

THE USE OF PSYCHIATRIC SERVICE DOGS WITH SOLDIERS WHO HAVE PTSD

Craig T. Love (1) and Joan Gibbon Esnayra (2)
(1) Westat, Inc. and (2) Psychiatric Service Dog Society

Psychiatric Service Dogs are trained to meet the disability-related needs of persons living with a variety of mental health disabilities, including post-traumatic stress disorder. The Psychiatric Service Dog concept originated in 1997 when a group of mostly civilian mental health consumers gathered online to discuss the role of dogs in refractory symptoms management. Many reported in hindsight that their dogs could sense oncoming episodes of mental illness even before the patients themselves could perceive a change within their own bodies.

The Psychiatric Service Dog intervention is a form of Mind/Body CAM. It is currently being recommended by clinicians throughout the country as an adjunct to ongoing conventional mental health care treatments. A recent survey of persons utilizing Psychiatric Service Dogs demonstrates that 82% of those with a PTSD diagnosis report symptom reduction after partnership with a Psychiatric Service Dog. Another 40% report that their use of medication has decreased subsequent to human-canine partnership.

The proposed study has two aims: (1) establish the effect size in a small “seedling” project for application to a larger project testing the effectiveness of the Psychiatric Service Dog intervention for soldiers and veterans who are disabled by PTSD, and (2) assess the feasibility of implementing a Psychiatric Service Dog training program at a military medical facility for soldiers and veterans who are disabled by PTSD.

The Psychiatric Service Dog Society, Westat, and Walter Reed Army Medical Center (WRAMC) propose a collaborative 18-month “seedling” study that compares mental health outcomes over a 12-month period between two groups of soldiers disabled by PTSD. One group of 10 soldiers will receive a dog and professional training. Another group of 10 soldiers will not receive a dog or professional training. Both groups will undergo the usual treatment protocol for soldiers with PTSD at WRAMC.

Both groups of participants will be assessed by Westat clinicians at baseline and every 3 months thereafter for a total of 12 months (5 data points total). Baseline assessments will include the Clinician-Administered PTSD Scale (CAPS), the Mississippi Scale for Combat-Related Posttraumatic Stress Disorder (35 items), the Posttraumatic Stress Disorder Checklist (17 items), and an abbreviated version of the Society’s PSD handler survey (60 items). Thereafter at 3-month intervals, all participants will be assessed by Westat clinicians using the Posttraumatic Stress Disorder Checklist (17 items). There also will be a panel of biological markers collected in unobtrusive procedures to monitor indicators of PTSD at each of the 5 data points.

The primary statistical techniques to be used to compare the two groups will be repeated-measures analysis of variance (ANOVA). This is the best way to make use of the 5 planned assessment points to increase the power of the statistical tests and will permit an examination of the average trajectories of change in the two groups.

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