



# Service Dogs for Veterans with PTSD: A Randomized Clinical Trial

NCT01329341

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## 1. Introduction to Application

Not applicable

## 2. Research Plan

### Specific Aims

Service dogs (SDs) is an umbrella term that encompasses a variety of trained dogs which assist individuals with disabilities. The training of these dogs can vary – from highly trained medically-necessitated service dogs to well-trained domestic pets that provide emotional support and comfort to their owners. Although the benefits SDs afford their partners have been examined previously as a means to aid functional tasks, SDs may also provide constant companionship, enhanced feelings of personal safety, and serve as social connections with others.<sup>1,2,3,4,5</sup>

This proposed three-year, *longitudinal study* will follow individuals with PTSD newly partnered with SDs (SD Group). Participants will be recruited from the Tampa VA catchment. All participants will be asked to complete questionnaire packets at baseline, three, six, nine, twelve, eighteen and twenty-four months after enrolling in the study.

### Research Questions and Hypotheses:

*Specific Aim 1: To determine the impact of service dogs and determine who benefits the most.*

**Hypothesis 1A:** Individuals partnered with SDs will have greater improved mental health over time (Primary outcome will be the PCL checklist. Secondary mental health will be quantified by scores on depression and alcohol use).

**Hypothesis 1B:** Individuals partnered with SDs will have improvements over time in secondary factors of physical, psychosocial, and socioeconomic variables. The secondary factors are defined as follows: 1) physical factors: co-morbidities, medication use, sleep 2) psychosocial factors: community participation, quality of life and 3) socioeconomic factors: demographic and health care utilization and out-of-pocket health care expenses.

*Specific Aim 2: To determine costs associated with total health care utilization and mental health care utilization among Veterans with mental health disorders needs and service or therapy dogs.*

**Hypotheses 2A:** Individuals partnered with SDs will have decreased mental health care utilization over time.

**Hypotheses 2B:** Individuals partnered with SDs will have decreased total health care utilization over time.

*Specific Aim 3: To determine recommendations for providing service dogs to Veterans.*

Develop a strategic plan to provide service dogs to Veterans. A consensus meeting will be planned and will include all investigators of the project along with key individuals from funding agency to discuss findings of study.

*Secondary Aim:* To compare study findings to another VA funded study that is providing dogs as pets to Veterans with PTSD. Both studies are using similar measures to assess mental and psychosocial factors. Data will be compared across groups (SD to dog as a pet) to determine if the highly trained dogs help the Veteran more than having a dog as a pet.

*Projected Time Table*

Training of SDs is time intensive and expensive, with limited numbers of dogs who actually graduate. We will work with vendors to obtain the dogs, but recognize that there may be a significant waiting period prior to pairing. To demonstrate maximum treatment benefits, the data collection phase of this three-year study will be conducted for a minimum 18 months (maximum of 24 months for early enrollees) as we feel the acclimation period for the human-animal bond is longer than 18 months. This allows sufficient time for statistical analyses.

*Timeline*

TASK	YEAR 1				YEAR 2				YEAR 3				YEAR 4				YEAR 5			
	Apr 2011	June 2011	Aug 2011	Oct 2011	Jan 2012	Apr 2012	Aug 2012	Oct 2012	Jan 2013	Apr 2013	Aug 2013	Oct 2013	Jan 2014	Apr 2014	Aug 2014	Oct 2014	Jan 2015	Apr 2015	Aug 2015	Oct 2015
Start up activities, finalize data collection forms, hire and train data collectors	Shaded																			
Renewal training for data collection				Shaded			Shaded													
Advertisement/promotion of study	Shaded	Shaded	Shaded	Shaded																
Recruit participants, collect baseline	Shaded	Shaded	Shaded	Shaded	Shaded															
STUDY HOLD**					Blue	Blue	Blue	Blue	Blue	Blue										
Collect 3-, 6-,9-, 12- 18- and 24-month data on enrolled veterans			Shaded	Shaded	Shaded	Shaded	Shaded	Shaded	Shaded	Shaded	Shaded	Shaded	Shaded	Shaded	Shaded	Shaded	Shaded	Shaded	Shaded	Shaded
Enter data in electronic database and conduct on-going verification			Shaded	Shaded	Shaded	Shaded	Shaded	Shaded	Shaded	Shaded	Shaded	Shaded	Shaded	Shaded	Shaded	Shaded	Shaded	Shaded	Shaded	Shaded
Conduct statistical analyses and summarize findings																				
Apply for additional funding to support follow up work																				
Dissemination of Findings																				
Prepare manuscripts																				Shaded

\*\* Because of ongoing vendor issues, enrollment was stopped for a second time and new vendors have been awarded contracts. Study will extend beyond the three year period utilizing Veterans who signed consent prior to second hold.

### *Background and Significance*

An estimated 16,000 individuals are partnered with SDs today.<sup>6</sup> In the early 2000's, the cost of raising and training these highly skilled dogs, who typically work for eight years, is estimated to range from \$8,500 to \$15,000.<sup>7,8</sup> Current estimates (from conversations from a variety of vendors) is around \$23,000. Section 2 of Bill H.R. 2792, the Disabled Veterans Service Dog and Health Care Improvement Act of 2001, allows the VA to reimburse costs of SDs and associated training for qualified Veterans.<sup>9,10,11</sup> An additional bill was passed in 2010, Bill S.1390, sec 1084 which authorized appropriations to conduct a pilot program on use of service dogs for the treatment or rehabilitation of Veterans with physical or mental injuries or disabilities. This pilot program is to be implemented "120 days after the enactment of this Act, and a three year pilot program to assess the benefits, feasibility and advisability of using service dogs for the treatment or rehabilitation of Veterans with physical or mental injuries or disabilities, including post-traumatic stress disorder (PTSD)" is to be completed.<sup>12</sup> Due to the previous research conducted by the principal investigator (PI) of this proposal, the research team has chosen to focus on PTSD and subsequent mental health improvements which may result from provision of a service dog.

Although some studies have been completed, the research that has been conducted to date has not been designed or controlled in ways that bring us closer to the use of SDs becoming empirically supported treatments. Study samples tended to be small, unrepresentative and heterogeneous, and without adequate control groups. In going forward, of utmost importance is the careful definition of the population under examination and what is to be measured, as well as a need for controlled designs and stated outcomes that are relatively impervious to expectancy and demand effects, and to self-report or personal interest biases. Additionally, most studies have reported on the positive benefits that are observed while in the context of the therapeutic milieu but have not examined whether these effects carry over into other contexts or if they are retained over time. Rigorous efficacy and effectiveness research is needed.

*Background of Service Dogs:* The use of dogs to assist individuals with disabilities began over twenty years ago, and has subsequently flourished.<sup>13</sup> According to the American with Disabilities Act (ADA), if a dog has been individually trained to 'work or perform tasks for the benefit of a person with a disability' it is considered a 'service dog'.<sup>14</sup> Furthermore the ADA defines disability as a 'mental or physical condition which limits major life activity' which would include items such as caring for one's self, walking, seeing, hearing, working, and psychiatric conditions. The dog must be trained specifically to the person's disability. Service animals (including SDs) are legally defined and are not considered 'pets'. International Association of Assistance Dog Partners (IAADP) includes Psychiatric dogs under the umbrella of service animals<sup>15</sup> Therapy animals are not legally defined by federal law. They are typically personal pets of their handlers and work with their handler to provide services to others.<sup>16</sup> Therapy dogs are typically used in facilities or as Animal Adaptive Therapy. Various service dog agencies, though train dogs to be companions to individuals with mental health disabilities and refer to them by a variety of names including skilled companion dog, special needs therapy dogs, and

social/therapy dogs. Presently an estimated 16,000 individuals use a SD for mobility related impairments.<sup>15, 16</sup> As limited research exists, the characteristics of this group are relatively unknown, including the distribution of disabilities and demographics of the population. Depending on the type of service dog, various aids are provided. For example, mobility SDs provide aid with mobility-enhancing and energy-saving tasks: pulling wheelchairs, assist with transfers, open doors, turn light-switches on and off, and retrieving objects (e.g., telephone, towels, clothing).<sup>2,3,4,5</sup> Psychiatric service dogs provide aid in assistance of a medical crisis, treatment related assistance, assistance coping with emotional overload, and security enhancement tasks.<sup>15</sup>

Additional sections of this background focus on research that currently exists which justifies why we are examining certain outcomes. The remainder of the background section is divided into four sections encompassing 1) Mental Health and PTSD, 2) Mental Health and Service Dogs 3) Service dog impacts on secondary factors: Physical, Psychosocial, Economic and 4) Service dogs and Healthcare Utilization.

*Mental Health and PTSD:* Epidemiological studies with civilian populations, including the largest of which is the National Co-morbidity Survey-Replication (NCR-S), show that the lifetime prevalence of PTSD is 6.8% in the United states, with women outnumbering men almost 3-to-1 (9.7% women, 3.4% men).<sup>17</sup> Surveys of base rates for PTSD in military personnel returning from wars in Iraq and Afghanistan have yielded a wide range of estimates. Rates have varied considerably, but large, convenience samples of deployed veterans have in general ranged between 5-20% for PTSD in non-treatment seeking veterans, while studies looking at veterans who are seeking treatment report rates as high as 50% for veterans who screen positive for PTSD.<sup>18</sup>

*The Use of the Diagnostic Interviews and Instruments in PTSD Studies:* The diagnosis of PTSD is reached when a trained clinician determines that the criterion for the disorder has been met according to agreed- upon symptoms. To aid in the reliable diagnosis of a psychiatric disorder structured clinical interviews have been developed which allow for increased agreement upon the classification of a diagnosis. The Clinician-Administered PTSD Scale (CAPS)<sup>19</sup> has become the gold standard for classification and determination of PTSD in trauma populations. It has been well validated has been used in hundreds of studies.<sup>20</sup>

Methods to screen for PTSD, as used in the above studies on prevalence, can vary from as little as a few items (e.g. 4 items on the PC-PTSD<sup>21</sup>, to the 17 items on the PTSD Checklist (PCL) which directly relate to the symptoms needed for diagnosis).<sup>20</sup> The screening instruments are extremely valuable, particularly when time, limited resources, or costs are factors that will not allow for a face to face clinical interview to be conducted. All such screening instruments are judged against the gold standard of the CAPS in determining how well they approach agreement in the reporting of symptoms or stating there is a case of PTSD present. While all screening instruments vary somewhat from the highest standard of the structured clinical interview, the PCL has been found to be a well validated and reliable instrument when assessing symptoms of PTSD across time.<sup>22</sup>

In addition to PTSD, common co-morbid psychiatric conditions can frequently occur. Vietnam Veterans have most commonly reported problems with depression, anxiety, and alcohol, among Veterans who had high levels of war-zone exposure being significantly more likely than those with low exposure to develop the disorders.<sup>23</sup> Depression and alcohol problems have continued to be common among returning Veterans, with rates ranging from 14% to 27%.<sup>24,25</sup> A related study, evaluating mental health problems among 88,235 US soldiers returning from Iraq, showed that 20.3% of active and 42.4% of reserve soldiers required mental health treatment, including treatment for alcohol problems, and that many reported a fourfold increase in concern about interpersonal conflict in a period of 3 months post-deployment, namely with family and significant others.

*Mental Health and Service Dogs:* Animal-Assisted Therapy (AAT), a form of SD, has been associated with a positive influence on individuals with psychiatric symptoms.<sup>26,27,28</sup> Recent work by Anonioli et al,<sup>29</sup> demonstrated that subjects with depression randomized to interaction with dolphins (vs. no dolphin interaction) demonstrated significantly decreased depression scores following exposure. Columbo et al.<sup>28</sup> demonstrated that among three groups of the institutionalized elderly, the group randomized to animal therapy demonstrated significant increased quality of life and decreased symptomology. Berget et al.<sup>26</sup> demonstrated in a randomized trial involving exposure to farm animals (vs. no exposure) among subjects with schizophrenia, anxiety disorder and affective disorders, the exposed group demonstrated significantly increased self-efficacy scores and quality of life scores.

Although research exists to document that depression is at increased levels in disabled population compared to that of the general population,<sup>30</sup> little of the SD research has assessed level of depression in study participants. Findings from previous grants conducted by the PI have shown that receipt of SDs, positively impacts the occurrence of depression.<sup>31</sup> In addition, Rintala et al.<sup>32</sup> found individuals newly partnered with SDs to exhibit modest improvements in depressive symptoms over a 6-month period of time. **Our study will use the PCL checklist as the main outcome and include measures of depression and alcohol use as additional primary outcomes. (Hypotheses 1A).**

*Service dog impacts on secondary factors: Physical and Psychosocial:* In the studies that have been completed to date on the use of SDs, the impact that SDs have on psychosocial outcomes have been examined at length. Most of the research conducted, has been completed on individuals who are using wheelchair SDs opposed to therapy dogs.

Physical: A similar relationship has been found for individuals who have PTSD.<sup>33,34</sup> In a recent sample of OEF/OIF veterans, a substantial number of Veterans who develop PTSD often have co-morbid chronic pain. One recent sample found that approximately 35% of chronic pain patients carry a diagnosis of PTSD,<sup>35</sup> while in a study of patients with low back pain, 51% of the patients evidenced significant PTSD symptoms.<sup>36</sup> A strong association has been found between the occurrence of pain, and problems with emotional and physical functioning in the returning OEF/OIF Veteran population.<sup>33</sup> There is a strong need to consider how these factors impact overall functioning and how treatments, including medical and psychotropic medication are utilized.

There have been a number of studies, on Veterans with PTSD which have reported poorer physical health, increased medical utilization, and greater work impairment than those without PTSD. Other studies in a civilian female population<sup>37</sup> found that the presence of PTSD accounts for significant functional impairment, beyond that of the physical aspect of the trauma. This was evident on measures of physical functioning, vitality social functioning and role limitations, with similar results in decreased general health, vitality and social functioning<sup>38</sup> in patients who still met criteria for PTSD, one year after enduring physical traumas that required hospitalizations and surgery. These findings highlight the association between trauma, presence of PTSD and greater functional impairments, which is often present in our Veteran population.

Psychosocial: Several studies have examined changes in self-esteem of individuals partnered with SDs. Rintala et al. found new SD partners (n=16) exhibited significant increases in self-esteem. In a cross-sectional survey of SD partners (n=202) conducted by Fairman et al., 4 participants self-reported increased self-esteem, confidence, safety and independence as well as better coping abilities.

Individuals with disabilities are less likely to be able to fully participate in their communities.<sup>39</sup>,<sup>40</sup> Excessive time spent in self-care and medical needs can limit the availability of, and energy to pursue, social and leisure activities. Eddy et al.<sup>41</sup> observed the public's behavior toward individuals using wheelchairs with and without their SDs. Significantly increased numbers of passerby smiles and initiated conversations were seen when the SD was present compared to when the dog was not present. These results were noted first with children and then with adults using wheelchairs in a variety of settings.<sup>41,42</sup> Assistance animals serve as social buffers by alleviating discomfort and awkwardness according to these studies.

### **Our study will examine secondary factors which encompass physical and psychosocial measures (Hypotheses 1B).**

*Service Dogs and Healthcare Utilization*: Popular belief holds that pet owners, especially dog owners, enjoy better health than their peers who do not own pets. Indeed, exposure to animals, especially dogs, has been shown to have positive physiological consequences,<sup>43,44</sup> leading to decreased health care utilization. Simply stroking a dog decreases physiological arousal, including lowering blood pressure,<sup>43,44,45</sup> decreasing heart rate and slowing respiration,<sup>46</sup> and increasing finger temperature.<sup>47</sup> Anderson et al.<sup>48</sup> examined a large sample of healthy clinic patients (n=5,741) in Australia and found that compared to individuals who did not own pets, pet owners (primarily dog owners) also had lower triglyceride and cholesterol level, in addition to lower blood pressure levels. In general, a national probability sample from Australia found pet owners to have better health and decreased health care utilization as measured by number of doctor visits and medication use.<sup>48</sup> Individuals who had companion animals visited the physician less often and used less medication according to other studies.<sup>49,50</sup> If touching a dog can have such a remarkable impact, what are the long-term effects of human-animal interaction, specifically partnership with an SD?

Very little data exists regarding health status and health care utilization of SD partners. A cross-sectional study of SDs partners (n=57, response rate 90 percent) conducted by Lane et al.,<sup>5</sup> found participants to report increased self-perceived health after receiving a SD, though most had

degenerative illnesses. Fairman et al.'s cross-sectional survey reported SD partners used 2.1 less hours of paid and 5.9 less hours of unpaid assistance each week after receipt of their SDs. The estimated cost savings due to decreased paid assistance hours was \$600 per year. Based on the previously mentioned estimate of 16,000 SD users in the United States, this represents a potential savings of \$9.6 million per year due to decreased reliance on paid assistance. Limitations in these studies include cross-sectional design resulting in recall bias of previous events and controversial studies.

Individuals with PTSD are significantly correlated with increased health care utilization, work disability, lower socioeconomic status, morbidity, and mortality.<sup>51,52</sup> Moreover, requiring assistance in activities of daily living (ADL) reliably predicts nursing home admissions, and as a result, has influenced state and federal healthcare policy. Limitations in ADL and instrumental activities of living IADL serve as eligibility criteria for public and private disability benefits as well as outcomes by which clinicians and researchers evaluate the efficacy of their interventions.<sup>43</sup> **The proposed study will examine healthcare utilization in relation to having a service dog (Hypotheses 2A and 2B).**

#### *Significance of Research*

VA hospitals nationwide are integrating service dogs into treatment plans for disabled Veterans. However, with the training of SDs taking up to nine months and costs estimated at \$23,000 per SD, the utilization of SDs as adjunct to mental health treatment is in need of investigation. This study will be the first to assess the impact of highly trained SDs on the psychological, behavioral and social functioning of a Veteran population.

The idea that the presence of animals can produce calming effects in humans is commonly cited in areas of stress reduction.<sup>53,54</sup> Also, relevant to internalizing disorders are unconditional positive regard as well as acceptance, which may help to promote an increased sense of self-efficacy and trust in others, as well as reduced feelings of rejection and inadequacy. Studies of the ability of animals to alter perceptions of social desirability and to increase positive social interactions between strangers have been uniformly positive.<sup>55</sup> It has also been cited that pets provide feelings of companionship, security, and of being loved.<sup>56</sup> It is thought that this occurs because animals provide an opportunity for emotional investment that is free of negative evaluation and not subject to feelings of rejection.<sup>57,58</sup> Finally, companion animals may promote the formation of secure attachment relations with another living being and thereby contributing to one's basic sense of trust.<sup>59</sup>

To date, there have been no long-term follow-up studies of the impact or efficacy of animal-assisted interventions. Although some have attempted to determine if changes in behavior could be observed beyond the context of the intervention (generally school and home)<sup>60,61</sup> the results are conflicting.

When considered alongside the large numbers of anecdotal statements attesting to the power of animals to hasten the building of rapport between patient and therapist, these findings have important healthcare implications. If the presence of an animal can make the therapist appear less threatening, it seems reasonable to believe that some patients would achieve a greater sense of comfort more quickly and remain in therapy. In addition to enhancing the patient's perception of



the healthcare provider, the presence of an animal provides a benign, external topic of conversation on which to focus, which may further hasten and enhance the development of a working alliance. Given that compliance and retention in treatment, as well as treatment outcomes, may be strongly related to the quality of the therapeutic relationship, this particular aspect of animal-assisted interventions merits urgent investigation.

The use of dogs as companions and an adjunct to current mental health treatment is quite promising. Professionally trained SDs can assist Veterans find misplaced items due to cognitive memory loss (e.g., wallet, cell phone, keys); perform functions to assist with PTSD symptoms (e.g., alert bark, safety check of rooms, position self between stranger and owner in large crowds); result in fewer doctor contacts; and serve as catalysts or mediators of human social interactions and may expedite the rapport-building process between patient and therapist.<sup>62,63</sup> Not only can a dog assist Veterans to meet physical challenges and proceed in therapy, but they can be utilized to overcome a lot of the mental instability that they feel.

### **Preliminary Studies**

The principal investigator (PI) has completed several pilot studies on SDs. An overview of the studies is provided below. NOTE: PI name changed in 2009 from Fitzgerald to Groer.

*Wheelchair Assistance Dog –Merit Review # D3078R* was completed expanding the pilot work of the PI. For sake of space, information on the pilot studies has not been included. This prospective study compared four groups over an 18-month period: those who had recently received a SD and those waiting to receive a SD, those who had pets and those who did not have a pet. All participants completed questionnaires at baseline (prior to receipt of dog), and at 3, 9, 12 and 18 months (post receipt of dog for the SD group). The questionnaires covered demographics, socioeconomics, health care utilization, and psychosocial characteristics (e.g., self-esteem, affect) as well as functional outcomes.

There were a total of 186 participants enrolled in the Merit Review study. Of these participants, 123 completed all five collection points over the 18-months of the study and 14 were withdrawn or dropped out by missing more than one questionnaire. The mean age was  $46.1 \pm 12.2$  years, having their disability/diagnosis for  $25.3 \pm 15.6$  years. Forty percent of the subjects had progressive disabilities ranging from multiple sclerosis to amyotrophic lateral sclerosis and 60% had non-progressive disorders such as cerebral palsy and spinal cord injury. The population was also comprised of 83.9% Caucasian and 62.9% female. 31.4% were actively employed. At baseline, groups were comparable in all outcomes. After all follow-up was completed, the only significant difference in psychosocial outcomes was found between groups with respect to depression ( $p=.047$ ). No other measures were significantly different between the groups for other psychosocial variables [fatigue ( $p=.342$ ), loneliness ( $p=.656$ ), positive affect ( $p=.088$ ), negative affect ( $p=.313$ ) or self-esteem ( $p=.129$ )]. Significant differences were also seen the occupational component of the Craig Handicap Assessment and Reporting Technique CHART tool ( $=0.025$ ). In both findings, those who were on the waiting list to receive the service dog were significantly more depressed and less functional (CHART) than the other groups.<sup>64</sup>

*Epidemiology of Service Dogs* was a second study funded by VISN 4 aimed to: 1) describe the population partnered with SDs based on the characteristics of the individual, 2) determine the association between of length of SD partnership and the individual characteristics and 3)

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compare the characteristics described above between individuals who have yet to receive a SD and individuals already utilizing a SD. Identical information was collected as described for previous study.<sup>65</sup>

Because of the large population that we recruited, we completed a secondary data analysis to examine sub populations. Of specific interest, was to determine if those individuals who required human assistance would benefit more from a SD. Of the 375 individuals who contributed data, 89% were Caucasian, 66.4% were females with an average of 45.7 years old ( $\pm$  12.9) and a mean duration of injury or disability equaling 23.4 years ( $\pm$  14.9). One hundred sixty-four individuals (43.7%) owned SDs.

Significant differences were found between the two groups (those who had SDs and those who did not) with respect to functioning and community participation as measured by the CHART. People who had SDs had more cognitive independence ( $p=0.00$ ), were more able to participate in and maintain customary social relationships ( $p=0.00$ ) and had better mobility than their counterparts. Those partnered with SDs had higher positive affect scores ( $p=0.000$ ), but reported taking fewer medications than those individuals without SDs ( $p=0.000$ ). Individuals with SDs reported using more hours of paid assistance for instrumental activities of daily living (IADLs) – such as running errands ( $p=0.000$ ), than those without SDs. This suggests that if an individual requires functional help, SDs may be of benefit.<sup>66</sup>

*Hearing and Service Dogs: An alternative assistive technology:* A service directed project (#B3089R) was subsequently funded to examine SDs and hearing dogs (HD) as an alternative to assistive technology (AT). A combination of questionnaires and observation was completed to assess types of assistive technology including healthcare utilization and caregiver help questions as well as specific questions related to SDs.

Cost issues associated with AT: People partnered with a SD pay on average \$75 per month to care for their dog while the SD comparison group also paid \$75 per month for their AT needs. Although not statistically different, SD partners pay about \$188 per month for their AT devices ( $p=0.16$ ). However, these differences in costs associated with service dog versus AT devices is a function of disability and race ( $p=0.159$ ). In addition, participants partnered with a SD were asked if they had to make accommodations to their environment. Eighty-eight percent made changes to their surroundings and 74% had to pay for these changes out of pocket with the median total cost being \$400 and a range of \$10 to \$6,600. HD partners paid about \$100 per month to care for their dog in addition to an average of \$74 per month for the AT needs. In comparison, HD controls pay about \$145 per month for their AT needs. No significant differences were observed between these monthly costs ( $p=0.01$ ). When the HD individuals were partnered with their dog, 62% ( $n=8$ ) made changes to their environment and 75% of these individuals paid for their accommodations. The range of cost for changes was \$75 to \$2000 with a median cost of \$250.

Assistance dogs specific questions: For those individuals partnered with assistance dogs, additional questions were asked that were specific to the reliability and satisfaction of their dogs. For those with SDs, 90% reported being very satisfied with their dogs overall. Similarly, 82% were very satisfied with the agency from which they obtained their dogs, and 86% were very

satisfied with the training the agency provided for using their dogs. Eighty-five percent of the SD partners received follow-up training with their dogs and of these individuals, 81% were extremely satisfied with this training. Overall, about 86% of the population felt their SD was very reliable.

For those who were partnered with HD, 69% stated they were very satisfied with their dog, 77% stated they were very satisfied with the dog agency as well as the training they provided to work with the dog. Seventy-nine percent of the population partnered with HDs received follow-up training of their dogs, with 67% being very satisfied with this training. Eighty-five percent of the HD respondents rated the reliability of their HD greater than an eight on a scale of 1-10, with 10 being most satisfied ( $\geq 9$ ).

Very little data exists regarding changes in health care utilization of individuals partnered with assistance dogs. This study found that those with dogs were less likely to have visits to the doctor and spend less time than their counterparts. Although number of visits is a crude measure of healthcare utilization it still represents a potential that the impact assistance dogs may have on their partner. Research conducted on pets in general has shown that contact with them may actually decrease the occurrence of disease as well as decrease stress and anxiety. Within this respect, the dog is not only benefiting the individual from a technology perspective but also a psychosocial perspective.<sup>67, 68, 69, 70</sup>

### **Research Design and Methods**

#### *Design*

This 3-year, mixed methods modified, non-randomized trial will follow individuals for two years. Due to the inability to recruit veterans interested in participating in a control (no dog) group, this group has been eliminated going forward with the study. The study will examine the influence of SDs by assessing the longitudinal change in mental health assessment over time among veterans who have PTSD. The group will consist of individuals partnered with SDs. Following initial screening for inclusion criteria, including criteria set by dog vendors, subjects who are eligible will receive a SD. This study will measure changes over time in the primary outcome of mental health. Additional outcomes in psychosocial health and healthcare utilization will be included. Recruits successfully completing the screening process will be placed on a vendor's waiting list to receive a SD upon the dog's completion of training. Recruits who do not meet all criteria, including vendor criteria, will be ineligible to participate..

Data will be collected at baseline and at 3, 6, 9, 12, 18 and 24 months for individuals with service dogs. For those awaiting service dogs, repeated assessments will occur every 3 months until obtaining a SD. Once baseline data has been collected for 24 months, assessments will occur every 6 months until the Veteran is paired with a SD. Baseline data will include detailed information on the characteristics of the participants, their mental health, psychosocial well-being, socioeconomic and healthcare utilization characteristics. As we want to obtain information regarding the changes in health and wellbeing over time, a prospective study will permit this type of comparison.

*Sample:* The study will use a convenience sample of VHA patients who are currently in treatment for PTSD. We have chosen to use these criteria as a safety measure for the veteran and the dogs. At this time, there are currently 600 veterans receiving care at James A. Haley VAMC for PTSD, with an estimated 25 new veterans seen in the clinic per week. We are confident that an adequate number of Veterans will be recruited for the study. We will monitor recruitment and retention numbers on a monthly basis. The use of additional VA hospitals as a potential source for recruitment is the contingency plan should we be unable to meet enrollment numbers.

We will be enrolling up to 220 Veterans to be paired with service dogs. The previously cited longitudinal study had only an eight percent attrition rate. Although similar methods are included in this proposal, we recognize that this is a different population; we will plan on a higher attrition rate. Thus, we are estimating a 15 percent drop-out rate ( $n=33$ ), and we will over-recruit participants. Up to two hundred and twenty participants will be recruited over the course of the study. These recruitment numbers are chosen with the expectation that *200 individuals* will complete the study.

A repeated measures design with one fixed effects (any one covariate [TBD]) and 1 within subject effect (time; each subject is measured 5 times [minimum]) achieves approximately 100% power to test the primary fixed effect (dog group status) if a Geisser-Greenhouse Corrected F Test is used with an alpha level=5% and the actual effect  $SD=0.47$  (effect size=5.54). Further, this design achieves approximately 100% power to detect a significant effects among both covariates (alpha level=5%,  $SD=0.8$ ; effect size=5.54) and significant interaction between both the primary fixed effect (dog group status) and each of the covariates (alpha level=5%,  $SD=0.8$ ; effect size=5.54). This analysis assumes a 1st order auto correlation between repeated assessments equal to 0.80.

To assure that we recruit sufficient sample size, we will initiate the following strategies: (1) carefully consider respondent burden when finalizing the baseline survey and interview schedule, (2) employ and train research assistants/data collectors with previous experience in collecting data and who have good communication skills, (3) provide a small reimbursement (\$10.00) for participant time and effort each time a questionnaire is returned, (4) develop posters and recruitment flyers which will be displayed in all mental health clinical areas, and (5) provide in-services on a regular basis to the PTSD and other mental health clinicians explaining the study. These methods have been used successfully in the past by the research team.

The investigators will track all subjects who contact them for potential participation in the study. Reasons for individuals deciding not to participate will be tracked. In the past, reasons that have been recorded include time, and effort to make appointments. The eligibility criteria will also be tracked so that a description of the population and who met criteria to enter the study (or not) can be described for future publications. These methods are used in all studies that the PI conducts.

To assure that we retain sufficient sample size, we will initiate the following strategies: (1) coach the research assistants in establishing rapport during all contact (in person and telephone), (2) reminders sent in advance of in-person interviews and packet of information sent to participant two weeks prior to the time of their scheduled interview, alerting the participant that we will be calling, (3) at the end of all visits, provide the participants the phone number with which to contact researchers should they have to change their next visit, as well as provide the name and

phone number of the supervisor should they have problems (4) send out a thank you card once a year to let participants know their efforts are appreciated, (5) keep the interviews to a minimum to lessen respondent burden, and (6) conduct quality assurance for the visits to assure that participants are being interviewed appropriately. These methods have been used successfully in previous studies conducted by the PI.

#### *Inclusion/Exclusion Criteria*

<b><i>Inclusion Criteria</i></b>	<b><i>Description</i></b>
Age	Age greater than or equal to 18 years
Referral	Referral from VA provider which documents PTSD diagnosis.
PTSD	PTSD symptoms as documented in the clinician referral letter.
Treatment for PTSD	In active treatment for PTSD for at least three months at time of enrollment and remain in treatment throughout the duration of the study. Participation will be verified quarterly to ensure that the veteran is still in treatment.
Acceptance by the dog vendor	Will be a function of the vendors that agree to provide dogs.
Dog care	Ability to adequately care for a dog, physically/financially. Has suitable home environment to provide for a dog. Has someone to care for a dog in the absence of the Veteran.
Travel to vendor	Willing and able to travel to vendor location by air or car for pairing
Geographic location	Living the state of Florida

<b><i>Exclusion Criteria</i></b>	<b><i>Description</i></b>
Mental Health Hospitalization	Veterans will be excluded if they have been hospitalized for mental health reasons in the prior 6 months.
Residence	Not living at the same residence for 6 months. It will be emphasized to the subjects to try and maintain the same residency throughout the duration of the study. Rationale is to ensure access they have appropriate follow up available to them both clinically and for the service dog.
Specific Diagnoses/conditions	Psychoses, Delusions, dementia, active alcohol/substance abuse or dependence, moderate to severe TBI as documented by chart review, suicide flag in CPRS. Study staff identifies a social, mental, or physical condition that prevents the Veteran from giving informed consent or participating in the study

Active suicide /homicide	At time of entry – Active suicide/homicide plan or intent, cognitive disabilities that would preclude safety of animal and ability needed for participation in the study
Children under 10	Veterans with children under 10 years of age in the home for more than 8 hours per day one day a week or more will be unable to participate.
Dual Enrollment without approval	While in this research study participants are required to check with the study team prior to enrolling in a secondary study. Taking part in other research studies may invalidate the results of this research, as well as that of the other research. As a result, participation in this study may be terminated.

### *Participant Recruitment and Informed Consent*

A HIPAA waiver will be obtained for the project manager to review CPRS to identify Veterans who are under treatment for PTSD. A list will be generated of Veterans and letters will be mailed to inquire about the Veteran's willingness to participate in the research study. Veterans will be directed to respond to the project manager of the study either via return mail or calling the 1-888 number available for the Center of Excellence. The project manager and/or data collectors will coordinate the timing of the screening visit. Flyers (which are already approved) will be provided to clinicians and other professionals that work for the VA and dog vendors that are providing dogs so that they may be distributed to Veterans. The flyer will also be printed as posters, to enable hanging in relevant areas of the hospital. If needed, veteran organizations (e.g. Paralyzed Veterans of America (PVA)) will be asked to print/distribute flyer in their newsletters. Other methods of recruitment will include posting announcements on relevant websites (e.g. PVA) to advertise the research study.

Opposed to matching, we will use a modified statistical method, minimization,<sup>71</sup> that facilitates equalizing study groups to assure similarity of disease characteristics, gender, and age. Similar to stratified sampling, our modified minimization technique involves examining groups to determine distribution of participants in selected confounding variables such as progressive and non-progressive disabilities. When an imbalance in such a variable occurs, recruitment will be aimed at the group with the lesser number of participants. This method will help minimize possible confounding variables, thus improving the validity of conclusions drawn.

*Screening Visit:* Once a Veteran has agreed to participate in the study, they will be asked to participate in a screening visit. Once the informed consent process is finalized, eligibility criteria will be confirmed. A review of CPRS records will be conducted by the study team to verify the Veteran truly meets all criteria. At this time, if all criteria are met, all baseline questionnaires will be completed and field notes taken. For safety reasons, Veterans who have children younger than 10 years of age in the home for more than 8 hours per day, one day per week or more will be excluded from the study. After 20 dogs have been placed without incident, this criterion will be revisited to potentially allow these Veterans to participate.

- The study team will perform a home evaluation visit prior to referring Veterans to a vendor. This visit will be to ensure the environment is safe and suitable for a

dog. A home environment checklist has been developed and will guide the study team in assessing the environment. An information sheet that provides details to Veterans regarding why and how the home visit will be conducted will be provided to Veterans when Informed Consent is obtained. During the visit, the team will check to see that there is an area for a dog to exercise, relieve itself, sleep, as well as making sure hazardous plants or chemicals are not within reach of a dog. All family members that will be living in the home will be expected to meet with the study team to ensure they understand the study requirements and are on board with bringing a dog into the home. If any issues are identified by the study team during the home evaluation the Veteran will have 3 weeks to fix the issues and reschedule a follow up home evaluation visit. If during the follow up home evaluation the study team determines that the issues are not fully resolved the Veteran will have one additional week to remedy the issues and reschedule a final home evaluation. If the issues remain unresolved the Veteran will be withdrawn from the study. Once the home evaluation has been approved the Veteran will be provided with contact information for the vendor. The Veteran will be instructed to contact the vendor and will be placed on the waiting list. The Veteran will be encouraged to review home owner/rental insurance policy to include a dog and be required to obtain a license for their service dog per local laws.

At this time, three vendors have been awarded contracts to provide dogs for this study. The RFI which was posted by the Contracting Office for the provision of service dogs for this project states “The National Defense Authorization Act for Fiscal Year 2010 specifically states, under Sec. 1077., Department of Veterans Affairs Use of Service Dogs for the Treatment or Rehabilitation of Veterans with Physical or Mental Injuries or Disabilities, para (b)(1)(B): The Secretary shall carry out the study by partnering with nonprofit 501(c)(3) organizations that are accredited by, or adhere to standards comparable to those of, an accrediting organization with demonstrated experience, national scope, and recognized leadership and expertise in the training of service dogs and education in the use of service dogs.”

Due to the concern that vendors could influence Veterans and thereby introduce bias, the interaction between vendors and Veterans will be limited. The study team will screen the enrolled Veterans to ensure vendor criteria are met. The vendors will require an interview to provide insight into the applicant’s personality and lifestyle, allowing them to match the Veteran’s personality and temperament with that of the dog they will receive. This interview may take place over the phone or in person, depending on the location of the vendor. Study team personnel may be present during this interview. The Statement of Work (SOW) provided to contracted vendors specifies that vendors are to limit their contact with Veterans to only what is necessary for assessment and training/pairing.

Once vendor screening and application is completed, vendors will provide input, based on their expertise as to who will qualify for a SD. The process for accepting the participant to receive a service dog will be a function of the vendor’s current practices. As previously stated, the study team will have the vendor’s acceptance criteria ahead of time to minimize the chance that a

Veteran will arrive to the training location and be turned away. This will help to avoid distress on the part of the participant by thinking they are getting a dog and then being declined.

Training of SDs for a specific individual takes time, and immediate placement of a dog with a Veteran most likely will not occur. Thus, baseline data collection will occur at the time of consent and every three months until the dog becomes available for the Veteran. If a Veteran completes 24 months of observation and is still not paired with a dog, assessments will continue every 6 months until a dog becomes available. If the Veteran is not been paired by 48 months they will be withdrawn from the study. Through observations and questionnaires we will ask the Veteran about how they feel, their mood, and their quality of life. During the waiting period, Veterans will be required to take an education course related to dog care and responsibility of dog ownership. This course will be provided by the study team and will be online through CITI or via paper copy. A paper copy of the Education Modules in the course will be provided to Veterans as a reference. Course content will cover all aspects of Service Dog ownership including grooming, health maintenance, and financial responsibility. A competency test will be given at the end of the course to ensure Veterans understand the material. If the Veteran fails to pass the test with a score of 80% or better, remedial training will be given by the study team and the test will be re-taken until passed. A Veteran Guide for Veterinary Care information sheet will be provided at this time as well. This Guide will contain information about health maintenance and when to take the dog to the veterinarian.

Once the study team receives word from a vendor that a SD is about ready for pairing, the Veteran and vendor will have an opportunity to talk to ensure that an appropriate match will be made. When the dog is ready, the Veteran will be required to travel to the vendor location. Travel may be by air or car, depending on the vendor location and considering the Veteran's preference when possible. If a Veteran drives their personal vehicle, he/she will be reimbursed at the government mileage rate upon completion of training and return home. Vendor staff will make travel and lodging arrangements for the Veteran. Lodging, air travel, and meals will be paid for by the vendor during the pairing (per Federal regulations) and reimbursed by VA per the SOW. The pairing process may vary by vendor and can last from one to three weeks.

Follow up visits after pairing: One week after bringing the dog home, the Veteran will be visited by the study team to ensure the transition into the home is going well and to ensure the safety of the Veteran and the dog. A SD Post Pairing Evaluation form will be completed. The Post Pairing Evaluation is an objective evaluation of the dog's health and behavior while the SD Questions speak to the Veteran's subjective feedback regarding the dog's behavior and their satisfaction with the dog. If concerns are identified, they will be addressed through additional home visits and training sessions with the VA trainer. After the initial questionnaire is completed, participants will be visited by the study team Dog Trainer or VA veterinarian months one and two to query the veteran about their dog's behavior. These interactions will be completed in person and a SD Post Pairing Evaluation form will be completed at each visit. If problems are noted, the PI will be notified and additional training will be provided by the dog trainer on the team. At months 3, 6, 9, 12, and 18, many of the same baseline questionnaires will be completed. For month 24, the same questionnaires completed at baseline will be administered. These questionnaires will be mailed to the Veteran or completed over the telephone. In addition, after receipt of the service dog, follow up home visits will occur at months 3, 6, 9, 12, 18, and



24. These follow up visits will be done in person and will encompass the data collector of the study and the VA dog trainer or veterinarian meeting with the Veteran and 1) collecting questionnaires if necessary, 2) watching interaction between Veteran and SD and completing the SD Post Pairing Evaluation and SD Questions, 3) completing an assessment of lethality which is standard operating procedure for clinicians to complete that no suicidal ideation or intent currently exists, 4) taking field notes, and 5) answering any questions should they arise. Correspondence between the Veteran participants and research team will be noted in a secure electronic database. If the assessment of lethality indicates problems, the Veteran's clinician will be called immediately. Veterans may be asked to meet with the Dog Trainer or veterinarian in a public setting (restaurant, park, etc.) so the Trainer or veterinarian can observe the dog's behavior in an unfamiliar setting. Periodic visits may be made to the Veteran by the funding agency to ensure safety and satisfaction of the SD. Questionnaires may be completed in person, mailed to the Veteran, or completed over the telephone.

The Veterans will be required to take their SD to their veterinarian for a wellness check every 6 months. The visits will start six months after receiving a service dog. Once per year, dogs will receive a comprehensive exam by their veterinarian. A Veterinarian Checklist will be provided to ensure a thorough exam is performed as required in the SOW. Veterans will provide the Checklist to their veterinarian during the visit, and the veterinarian will fax the completed form to the COTR. The fax will not contain any Veteran PHI and will be identified by the dog's name. Dogs will be taken to the veterinarian for health maintenance or for illness or injury as needed and Veterans will be asked to notify the study team any time the dog is taken to the veterinarian. VA will provide health insurance for the dog through a contract with Trupanion. Veterans will be provided with an ID card that allows them to use the veterinarian of their choice. All medical needs will be covered by this policy and the Veteran will have no out of pocket costs for healthcare related to the dog.

A Data Safety Monitoring Board (DSMB) is in place and will review reports provided by the study team to ensure ongoing safety of the veterans and SDs. The Board will advise and provide input and corrective measures as needed.

Completion of the questionnaire takes approximately one hour, and the questionnaires will be completed a total of six (6) times over the Veteran's 2 year participation in the study. All participants will be paid \$10.00 for their time and effort to participate in each of the data collection sessions. This includes the six visits that will occur after the baseline visit (total of \$70.00) as well as the data collection visits which will be conducted prior to delivery of the service dog. It is unknown how long it will take to have a SD placed with the veteran. Those who have been paired with a SD will receive \$75.00 per month for dog upkeep for the duration of their participation in the research study. This was written into the 'Bill', (and previously, we had not included it in the protocol). Veterans will be informed that payment may be received by mail or direct deposit into their bank account. In addition, veterans will be informed that payment may take up to 8 weeks to be received after completion of questionnaires and for the first \$75.00 payment. The study team will do everything possible to ensure timely payment. The funding agency may choose to visit Veterans to ensure their continued success in the study and dog pairing. In this case, Veterans will be paid \$10.00 for their time and effort.

We have chosen to follow individuals at these intervals, as we are building upon an earlier dog study framework. Although every effort will be made to contact participants at the scheduled times, there will be a 2-week window allowed from the target date to contact the participant. Should no contact be made, a second attempt to contact will take place 2-weeks beyond that to ensure that the participant still would like to participate. Although we originally planned to drop participants from the study should they fail to complete the questionnaire, this would entail the person having to give up their dog (if they were paired). We feel that with the in person visits with the individuals with service dogs as well as the less burdensome questionnaire, participants will be more likely to complete the surveys. To remove the dog from the veteran due to failure to complete questionnaire was deemed inappropriate.

*Intervention:* The vendor(s) will provide SDs for the Veterans enrolled in the study. The dogs will be trained according to their standards and will meet the criteria outlined in the Statement of Work (SOW). All dogs will be trained in basic obedience and a standard set of commands related to mitigation of PTSD symptoms. Due to previous vendor issues, the updated SOW calls for vendors to use only purpose bred dogs (no rescues) which have passed a thorough medical work up and have been “proofed” by a VA dog trainer with extensive experience in training dogs. Veterans will be expected to follow all directions from the vendor(s). Should a Veteran need hospitalization for mental health reasons at any time after they are enrolled, they will not be dropped from the study. Veterans must remain in active treatment for PTSD for the duration of the study. Any Veteran who stops receiving treatment for their PTSD symptoms will be dropped from the study and the service dog removed and returned to the vendor. To ensure Veterans are still in treatment, quarterly verification of mental health treatment will be done by contacting the Veteran’s clinician directly or reviewing the medical record..

Once a Veteran has completed their participation in the study, they may choose to keep their dog or return it to the vendor. If the Veteran chooses to keep their dog at the end of their study participation, they take full responsibility for the care of the dog. Neither the study nor the VA provides further support to the Veteran to care for the dog upon completion of the two year period. If keeping their dog, Veterans may be required to return the dog’s service vest to the vendor who provided it. Once out of the study, the Veteran will be able to contact the vendor directly and receive any follow up services provided by the vendor. Such services may include training support, supplies, support groups, or other services.

*Dog removal:* There may be instances when a dog would be removed from a Veteran’s care after pairing. Quarterly home visits will be done to evaluate the status of the pairing and to ensure the safety and wellbeing of the dog and the Veteran. If there is evidence of mistreatment of the dog, it will be removed from the Veteran and returned to the vendor per the SOW. This evidence includes signs that a dog has been hit or kicked (cowering, shaking in the presence of the Veteran or a family member, head shyness), very low weight in the absence of a medical condition, skin sores in the absence of a medical condition, the dog stays away from the Veteran or a family member, evidence that the dog has been tied to an object outside (neglect), gross parasite infection (fleas, ticks), and any other circumstance that would show neglect or abuse.

Sometimes, pairings fail because a bond cannot be established between a dog and a person. Vendors are experts at matching human and animal personalities to limit the possibility that this would happen. Based on information from vendors, a failure will usually occur within the first two weeks after returning home with a dog. In the case of a failed pairing within the first two weeks, the VA dog trainer will intervene and inform a Contracting Officer Representative (COR), who will inform the vendor. Per the SOW the dog will be returned to the vendor and a replacement dog sought. The Veteran may be required to attend another training session at the vendor location. If a pairing fails due to lack of bonding more than two weeks after returning home, it will be assessed by the VA dog trainer and dealt with on a case by case basis.

If a Veteran chooses to withdraw from the study after receiving a dog, the dog will be returned to the vendor. If a Veteran is not being treated by a mental health provider after receiving a dog, they will be withdrawn and the dog will be returned to the vendor.

If a Veteran moves out of the state of Florida after being paired with a dog, the study team will meet with the Contracting Officer Representative, the Data Safety Monitoring Board, and the study sponsor to determine whether the Veteran can remain in the study or should be withdrawn. These situations will be handled on a case by case basis.

At the end of the two year data collection period the Veteran may decide not to keep his/her dog. If a Veteran chooses not to keep their dog, it will be returned to the vendor.

*Dog replacement:* Per the SOW, if a dog develops disqualifying health or behavioral problems at any time after pairing the dog can be returned to the vendor. The VA dog trainer and COR, who is a veterinarian, would evaluate whether the problems can be easily remedied or if the dog should be returned to the vendor. If another dog can be provided quickly enough a replacement dog will be provided to the Veteran. If a dog dies due to circumstances outside of the Veteran's control, such as a terminal illness, a replacement dog may be provided. The Veteran may be required to attend a second training session at the vendor location. These situations will be handled on a case by case basis to determine whether a replacement dog will be provided.

#### *Measurements: Outcomes and Independent Predictors*

The outcomes to be measured by this study will be grouped into four categories: mental health, physical, psychosocial and socioeconomic/healthcare utilization. Table 2 shows an outline of the study outcomes, predictor variables, and possible confounders to be obtained from all participants.

Table 2: Measurements

	<b>Constructs</b>	<b>Measures</b>	<b>Burden</b>
Mental Outcomes	PCL -S	PTSD diagnosis/symptom severity	5 minutes
	Depression	PHQ-9	5 minutes
	Alcohol use	AUDIT-C	5 minutes Time point: baseline, final
Physical Factors	Co-morbidities	Medical record,	None to subject**

	<b>Constructs</b>	<b>Measures</b>	<b>Burden</b>
	Medication	Type, class, dose	None to subject **
	Sleep	Pittsburgh Sleep Index and PSQI Amendment for PTSD	10 minutes
Psychosocial Factors	Health-related Quality of Life	SF12	10 minutes
	Community participation	Community Integration Questionnaire	10 minutes
	Demographic	Age, gender, race/ethnicity, marital status	5 minutes
Service Dog	Satisfaction Tasks	Behavior, Level of satisfaction with the performance of service dog and what tasks are completed	10 minutes Follow up visits 1, 2, 3 and thereafter; only after pairing
Economics	Socioeconomic factors	Employment, hours worked, years of education, health insurance, income	5 minutes
	Healthcare utilization	Number of visits to healthcare in previous 3 month time period, for both mental health and general health care visits	
	Healthcare costs	Out of pocket expenses, self-report of outside healthcare	10 minutes

### Other Forms

<b>Form</b>	<b>Purpose</b>	<b>When Completed</b>	<b>Who Completes</b>
Home environment checklist	Checklist to assess home environment prior to dog placement	Pre-pairing home visit	Study Team Dog Trainer
Dog Care Test	Test knowledge of dog care and responsibility	After completion of Dog Care Course	Veteran
Service Dog Post Pairing Evaluation	Assess pairing and identify potential health or behavior problems in dogs	One week post pairing, months 1, 2, 3, 6, 9, 12, 18, 24	Study Team Dog Trainer at home visit
Veterinarian Checklist	Assess dog's health	Once per year	Veterinarian caring for each dog
Veteran Guide for Veterinary Care	Provides information to Veteran about maintain dog's health	Provided when Dog Care Course is completed	Information provided to Veterans
Home visit information sheet	Provides information to Veterans about how and why the home visit is done	Provided after IC, prior to home visit	Information provided to Veterans

Service Dog Questions	Veteran's subjective report about the dog's behavior and Veteran's satisfaction with the dog	Months 3, 6, 9, 12, 18, 24	Study team member present at home visit
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Unless otherwise noted, all measures are completed at all visits.

\*\*Data for these items will be abstracted from medical record

Mental Outcomes: Outcomes for the main hypotheses will be measured with the following measure using the PTSD Checklist (PCL).<sup>72</sup> PTSD Checklist is a 17-item self-report measure of the 17 DSM-IV symptoms of PTSD. Respondents rate how much they were “bothered by that problem in the past month”. Items are rated on a 5-point scale ranging from 1 (“not at all”) to 5 (“extremely”). The PCL can be scored in several different ways. A total score (range 17-85) can be obtained by summing the scores from each of the 17 items. Although the CAPS was used initially for the study, it was decided by the research team with input from the funding agency that diagnosis of PTSD will be confirmed by referring clinician and eliminate stress of completing the interview for the veteran. For some of the veterans that are enrolled in the study, CAPS is available in their medical record. If it is available, we will abstract the information to further confirm the diagnosis.

*Alcohol Use Disorder Identification Test (AUDIT-C) and/or Addiction Severity Index –Alcohol Use Disorders Identification Test (AUDIT)-C is a 3-item paper and pencil alcohol screen to identify hazardous drinking or those with problematic alcohol consumption use (abuse and dependence). There is a five-point scale ranging from 0 to 4. The items are summed to obtain a total score ranging from 0-12. For men, a score of 4 or more is considered positive. For women, a score of 3 or more is considered positive. Internal consistency reliability has been reported as 0.80.<sup>73, 74</sup>*

Physical factors: Physical factors will include items that can be drawn from the medical record (co-morbidities, medications). Abstracting medical record data at least one year prior allows for an evaluation of trends or sudden departures from normal care or medication profiles. *In addition, we will track the number of visits and type of therapies that the subjects will be participating in while in treatment for their PTSD.*

*Pittsburgh Sleep Quality Index (PSQI) is a 24 item self-administered survey used to assess sleep-related problems during the past month. The first 19 items are completed by the subject and there are five items completed by a bed partner or roommate. The five items answered by a bed partner or roommate are used as clinical information and are not included in scoring. The first 19 items are grouped into seven components (sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction) each weighted equally on a 0-3 scale. The seven component scores are then summed to yield a global score, which has a range of 0-21; higher scores indicate worse sleep quality<sup>75</sup>. The seven component scores of the PSQI had an overall reliability coefficient (Cronbach's  $\alpha$ ) of 0.83. We will also be using the PSQI-A, addendum for PTSD. The PSQI-A asks an additional ten questions that target PTSD-related sleep problems.*

Psychosocial factors:

*Community Integration Questionnaire (CIQ)* consists of 15 questions focusing on community integration behaviors. The CIQ is used to assess integration behaviors in the home, in social settings, and in productive activities such as employment and education. Items are scored on a 0-2 scale and scores can range from 0-29. A high score indicates greater independence and better community integration. The CIQ has been reported to have excellent internal consistency (Chronbach's  $\alpha = 0.76$ )<sup>76</sup> and test-retest reliability (0.96)<sup>77</sup>.

*Health Related Quality of Life will be assessed by the SF12.* This is a subset of the SF-36, a generic health status measure that has been shown to be valid and reliable in a wide variety of health care settings.<sup>78,79</sup>

Socioeconomic Factors: Factors of socioeconomic status will include items related to demographics (e.g. age, gender, marital status) and economic items which will include years of education, type of employment and occupation, income (self and household), type of health insurance carried, and number of individuals living in household.

Healthcare utilization: will encompass out of pocket expenses, and asks number of visits to health professionals over the past year (an average per month will be determined), average annual out-of-pocket healthcare expenses, current prescription medication used, etc.

*Data Management and Statistical Analysis*

Data Management: All data will be entered into a database developed for this project. Prior to data entry, all data will be reviewed for inconsistencies and missing values. All variables will have limitations imposed (range checks for high and low limits for the variable values). The database is password protected for confidentiality and data entry personnel will have read only access, so that data can be entered, but fields cannot be manipulated without investigator permission. A data safety and monitoring plan will be implemented to ensure no changes in the benefit/risk ratio occur during the study, and that confidentiality of research data is maintained. Investigators, study personnel, and the clinical coordinators involved in the study will meet monthly to discuss the study (e.g., study goals, progress, modifications, documentation) and address any issues or concerns at these meetings. Any instances of adverse effects will be reported immediately using the standard forms and/or procedures set forth by the Institutional Review Board. In addition, clinical coordinators from the Institutional Animal Care and Use Committee (IACUC) will periodically review study documentation and/or consent forms to ensure the safety and well-being of the dog participants.

Federal laws state that we must keep study records private. We will keep the records of this study private and confidential by locking them in a cabinet within a locked office in a secure building. Data will be maintained on a secure computer with encryption. Consent forms and notes will be transported back to the James A. Haley VA via locked security bag. All data collected will be maintained and stored according to VA regulations.

All computer data will be encrypted to protect patient confidentiality. VA and other Federal privacy, confidentiality and HIPAA regulations will be strictly adhered to. Data will be secured on a VA server behind VA firewalls, and access will be password protected and restricted to a limited number of study personnel. Fax machine available will be secured. All information collected by agencies shall be kept securely by the agency.

**Analysis:** The distribution of each variable will be examined for outliers to determine if transformations (to normalize data) are necessary. Initially, means  $\pm$  SD, and medians, will be calculated for all continuous measures (e.g., age, psychological scales). Frequencies and percent will be determined for categorical variables (e.g., gender, race, etc.). Variables considered ‘confounders’ (demographic and dog predisposition questionnaires) would be compared across time for the relevant hypotheses. Categorical variables (e.g., gender, race, disability) will be compared across groups using chi-square. Continuous variables (years of disability, dog predisposition scores) will be compared using ANOVA. Baseline differences will be noted and controlled for in additional analyses. A significance level of ( $\alpha < 0.05$ ) will be used for all analyses. All data will be managed as intent to treat.

Statistical Analyses are presented below by hypothesis:

**Hypothesis 1A:** *Individuals partnered with SDs will have greater improved mental health over time.* Baseline data will be examined. Observed significant differences will be used as covariates in modeling, they will be controlled in subsequent analysis. For this hypothesis, a linear repeated measures mixed model will be used to determine changes over time between groups. PCL-checklist scores will be considered the dependent variable. Baseline PCL-C scores will be introduced in all models as covariates. These scores are continuous. The use of mixed models allows for control of covariance data expected in clustered and repeatedly sampled data, and missing data. We expect the SD group to have greater functional independence and community participation at the end of the study.

**Hypothesis 1B:** *Improvements in secondary factors of physical, psychosocial, and socioeconomic variables will be seen in the SD group over time.* Variables within the physical (medication, comorbidities), psychosocial (affect, depression, loneliness) and socioeconomics (healthcare utilization) will be compared over time and will be assessed for each variable of interest using a repeated measures mixed model for dependent variable (DV) scored a continuous scale and generalized estimating equations (GEE) models for DV variables scored as a categorical. Dependent variables for all models will be scale or subscale scores. The within-participants variable will be the score at each time point (baseline, 3, 9, 12, 18 and 24 months). If significant differences exist at baseline for any confounding variables, that factor will be controlled for in the analysis. We expect to show improvements in all characteristics over the course of the study.

We will also complete a multivariate logistic regression to determine predictors of success (dichotomized higher scores after 18 months on function and participation). We expect that improvements in psychosocial factors (e.g, community participation) will result. We expect the data to be normally distributed; therefore, linear regression will be used. Results from the previous hypotheses (1B) will be used to determine which predictor variables are entered into the regression model; any variable with a  $p$ -value less than 0.10 will be considered. Highly related variables will be entered into the model separately. Any confounders significant at baseline will

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be controlled for in the models. In addition, we will repeat the multivariate logistic regression analysis described above with group (SD vs. control) as a primary fixed variable. We expect that subjects paired with a SD will demonstrate increased improvement in psychosocial factors.

We expect some individuals to benefit more than others. We hypothesize that individuals with greater limitations will have the most improvement when provided with an SD. Consequently, we will conduct a sub-analysis of the SD group. We acknowledge this is an exploratory analysis and the power is limited. The hypothesis we will test is individuals who score lower in psychosocial factors (e.g. community participation) at baseline will show greater improvements in those characteristic than individuals who scored higher. Therefore we will use the subcomponents scores of continuous measures and dichotomize them at a clinically meaningful point (e.g.,  $\geq 80 \geq 75^{\text{th}}$  percentile) at the baseline measure. All individuals will be put into one of two groups based on this cutpoint. Repeated measures analyses will be completed on all continuous variables with the between factor being the two groups and the within measure equaling variables of physical, psychosocial and economic characteristics.

In addition, we will conduct an exploratory analysis to determine whether relationships exist between group status (SD vs. control), demographic variables (age, gender, living arrangements, marital status, etc.) and the outcomes of interest – mental health (, PCL-C) and psychosocial factors (e.g. community participation). Categorical demographic variables will be analyzed using a chi-square for variables that are dichotomous, and one-way ANOVAs will be used for continuous variables that have multiple categories. Continuous demographic variables (e.g., age) will be compared to the outcomes using correlations: Pearson for normally distributed variables and Spearman rho for not-normally distributed variables. Sub-analysis will examine the relationship between the outcomes of interest and the physical, psychosocial and economic variables. Correlation analysis will be used to determine significant relationships. Two separate multiple regression models will be developed using any variables significant at a  $p$ -value  $< 0.10$  in the univariate analysis. The outcomes will be from the 18-month visit, whereas the predictor variables will be those recorded at baseline. These analyses will be used to describe those characteristics of Veteran's most likely to benefit from obtaining a SD compared to control subjects.

Power analysis for Hypotheses 1: All power analyses were completed with PASS 6.0<sup>81</sup>. Given a minimum sample size of 65 (per group), and an alpha of 0.05, we have over 80 percent power to detect differences in socioeconomic characteristics. This power analysis is based on changes in mean and SD (PCL-C) from prior published studies. This power analysis allows for the addition of three covariates to be added to the model.

***Hypothesis 2A:*** *Individuals partnered with SDs will have decreased mental health care utilization, over time.* We expect the SD group to experience diminished healthcare utilization over time. A within subject repeated measures will be completed to determine changes over time for healthcare utilization.

***Hypothesis 2B:*** *Individuals partnered with SDs will have decreased overall health care utilization, over time.* We expect the SD group to experience diminished healthcare utilization over time. A within subject repeated measures will be completed to determine changes over time for healthcare utilization.



*Exploratory Aim:* We will compare our findings to data collected in similar study entitled, “A Study of Dog Adoption in Veterans with Posttraumatic Stress Disorder” which is being conducted by Stephen Stern, MD at the South Texas Veterans Healthcare System in San Antonio, TX. This is a 2-year pilot study examining the use of shelter dog adoption as a supplement to standard care in reducing PTSD symptoms in Veterans. 24 veterans will be randomized to adopt a dog from the Humane Society while another 24 (control group) will be randomized to a wait-list and be eligible to adopt a dog after 3 months. Outcome measures will be assessed at baseline and at 3 intervals (1, 3, and 6 months post-randomization) for Veterans in the experimental group and 4 intervals (1, 3, 4, and 6 months) for those in the control group. Data collection will be in the form of face-to-face interview as well as self administered paper forms. CPRS records will be reviewed for changes in mental health treatments, medications, diagnoses, and other health related variables. Analysis will be completed which will examine similar measures (e.g. PCL checklist, depression, community integration) across our Veterans who received service dogs at three time points (baseline, three and six months) to their Veterans who received dogs as pets. As this is an exploratory analysis, power analysis was not completed.

### *Resources*

The James A. Haley Veteran’s Hospital in Tampa, Florida is a 341-bed tertiary care teaching hospital, with a 268 bed nursing home care unit, 50 domiciliary beds, and a 21 suite Fisher House affiliated with the University of South Florida. The HSR&D/RR&D Research Center of Excellence (COE), Maximizing Rehabilitation Outcomes, is comprised of 115 offices and 5 conference rooms. The new facility houses three clinical areas that serve patients, including the Falls Clinic, the Amputee Clinic and the Prosthetics Lab. The COE also contains the Consortium for Health Informatics Research (CHIR), one of seven national VA sites for research using text and data mining of the electronic medical record, and research methodology support for all studies. It is located five miles from the medical center and houses the necessary software and hardware for health services research including high-end personal computers, research software support, a T-1 connection to the facility’s servers and a restricted access shared network for data warehousing. A safety and data monitoring board will be formed to review study progress and ensure well being of the study participants.

### *3.0 Progress Report*

Not applicable

### *4.0 Human Subjects*

#### *1. Risk to Subjects*

- Human subject involvement and characteristics: Subjects will be asked to participate in this study for approximately two years which includes a screening visit, multiple baseline data collection pre intervention and additional follow up sessions at 3, 9, 12, 18, and 24 months. As described in the methods section, all subjects will be Veterans who are in treatment for PTSD at the Tampa VA. Inclusion/exclusion criteria is described in the methods section. All Veterans will be accepted into the study regardless of race and/or gender.

- Sources of Materials: Research material will be obtained from the subject's electronic medical record as well as data collected from the individual subjects. The data will be obtained specifically for research purposes.
- Potential Risks: This study is a minimal risk study. Subjects are required to complete questionnaires over 2 years.

## 2. Adequacy of Protection from Risk

- Recruitment and Informed Consent: Subjects will be recruited through direct referral as well as flyers in the Tampa VA PTSD clinic. Subjects interested in participation will contact the Project Manager. If eligible, the subject will be scheduled to come to Center of Excellence and complete a screening visit. If the subject qualifies, s/he will be asked to sign an informed consent by the Data Collector. The Research Consent will be noted in the subject's electronic medical record. Additional details of recruitment have been included in the methods section of the grant.
- Protection against Risk: On our research team, we have a psychiatrist who has extensive experience in individuals with PTSD. The psychiatrist will be available for help if needed. We have also built in methods to ensure that the SDs are being appropriately cared for throughout the study enrollment. This includes speaking to the Veterans 1 and 2 months after dog placement to ensure dog behavior is appropriate, visiting Veterans who are paired with dogs to ensure the pairing is appropriate, and completing the assessment of lethality at that visit to ensure Veterans continued well being. We also have contact information for all clinicians and their Service Chiefs, in the event we need to reach clinical help. We will be complying with agencies requirements that the SDs are only placed with eligible Veterans.

Subjects will be issued a coded identifier, which will be known only to the PI, data manager, and clerk. All records and the informed consent documents will be retained in locked files in the data manager's office. All computer data will be encrypted to protect patient confidentiality. HIPAA regulations will be strictly adhered to. Data will be secure on a networked computer system behind two firewalls, and access will be restricted and password protected.

- Potential Benefits of Research to Subjects and Others We do not know if there are potential benefits to subjects or others. We expect that those who receive the service dogs will receive benefits, but this study is being proposed to answer that question.
- Importance of Knowledge to Be Gained This clinical trial is the first to examine SDs with a Veteran population with PTSD. Prior to the OEF/OIF conflict, the VA had approximately 500 Veterans receiving services for PTSD, depression or other anxiety issues. As of April 2010, this has increased 200-fold, with over 87,000 Veterans in the

VA system receiving services for PTSD, depression or other anxiety issues. Of these, approximately 90% are OEF/OIF Veterans. Healthcare costs associated with mental health care in the VA are significant. From FY 1991-2000, the VA incurred approximately \$10 million dollars in costs associated with mental health care. Since the start of the OEF/OIF wars, these costs are estimated to be between \$7 and \$9 billion.

Mental health care among the OEF/OIF population is a priority for the VA, as the OEF/OIF Veteran population is growing exponentially. The VA Mental Health System of Care mission is to maintain and improve the health and well-being of Veterans through excellence in health care, social services, education, and research. There are many gaps in knowledge of the treatment and management of Veterans with chronic mental health issues, and research efforts are needed to address these gaps in an effort to lead to improved outcomes, and gain a better understanding of factors that impact health, function, and quality of life.

- Data Safety Monitoring Board (DSMB). In response to the adverse events, a DSMB has been formed. Members include veterinarians, a social worker, and a psychologist/statistician. The Board will meet quarterly via teleconference.

## 5.0 Vertebrate Animals

Although dogs will be used in this study, they will not be housed on VA premises. All training and placement of service dogs is completed by a contracted vendor (s). No experimentation will be done on any animals.

## 6.0 Multiple PI Leadership

There is only one Principal Investigator for this study.

## 7.0 Consortium/Contractual Agreements

There are none.

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