

AWARD NUMBER: W81XWH-15-2-0005

TITLE: Can a Canine Companion Modify Cardiac Autonomic Reactivity and Tone in PTSD?

PRINCIPAL INVESTIGATOR: Steven H. Woodward

RECIPIENT: Palo Alto Veterans Institute for Research

Palo Alto, CA 94304-0038

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Fort Detrick, Maryland 21702-5012

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13. SUPPLEMENTARY NOTES					
14. ABSTRACT We are actively acquiring and processing data that tests the impact of participation in the Service Animal Training Intervention program at the VAPAHCS-Trauma Recovery Program autonomic regulation, social experience, and social cognition in PTSD. Overall, recruitment has been on target, but enrollment in the intensive arm of the study has slowed due to canine medical and behavioral issues. New canines are expected to join the program soon and recruitment for this study arm is expected to return to previous levels. Preliminary results suggest an effect of canine companionship on attentional bias. Preliminary analyses of the impact of canine companionship on sleep and social behaviors are underway.					
15. SUBJECT TERMS Posttraumatic stress disorder, animal-assisted therapy, autonomic regulation, autonomic reactivity, mood, sociality, social cognition, sleep, ambulatory monitoring, defense response, facial affect					
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- 1. INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

The subject of this research is the impact of canine companionship on cardiac autonomic regulation, mood, social experience, and social cognition in U.S. Military Veterans undergoing inpatient treatment for deployment-related posttraumatic stress disorder. Its purpose is to confirm or disconfirm in such Veterans the positive impacts of canine companionship that have been reported in civilian samples. Its scope is the inpatient treatment context; however, its results may have implications for less severely affected populations and similar but less intensive interventions.

- 2. KEYWORDS:** Provide a brief list of keywords (limit to 20 words).

Posttraumatic stress disorder, animal-assisted therapy, autonomic regulation, autonomic reactivity, mood, sociality, social cognition, sleep, ambulatory monitoring, defense response, facial affect

- 3. ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

The major goals for this project as a whole were to perform strong tests of a set of hypotheses relating canine companionship to autonomic regulation, social experience, and social cognition.

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

The major goals for the second 12 months of this 4-year project were to recruit and test 74 participants. As described below, our recruitment stands at 76% of projected for the intensive limb of the design and 101% of the non-intensive limb. Efforts to remediate recruitment into the intensive limb will be detailed.

Enrollment since recruitment began in April 2015:

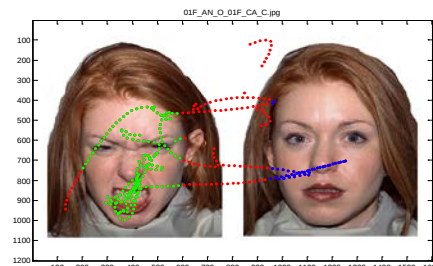
	Actual (n)	SOW target to date	SOW target final
Total Enrolled	110	129 (85%)	242 (45%)
Dog (intensive)	30	42 (71%)	80 (38%)
Non-dog	80	77 (104%)	160 (50%)
Total Completed	97	104 (93%)	200 (49%)
Dog (intensive)	26	34 (76%)	60 (43%)
Non-dog	71	70 (101%)	140 (51%)

Withdrawals (April 2015 – January 2017):

	Actual n (% of enrolled)	SOW expected to date n (% of enrolled)	Withdrawal reasons
Total Withdrawals	13 (12%)	26 (20%)	
Dog (intensive)	4 (13%)	13 (30%)	2 changed mind; 2 discharged early from clinical program
Non-dog	9 (11%)	8 (10%)	4 changed mind; 2 discharged early from clinical program; 2 clinically contraindicated; 1 ineligible

There have been no AE, SAEs, or UPs.

Our major finding to date has been that canine companionship is associated with modified visual attentional bias in Veterans with chronic severe PTSD. We rigorously assessed attentional bias towards aversive and pleasant visual imagery associated with the presence or absence of a familiar service canine in 23 veterans with chronic military-related posttraumatic stress disorder. Participants were repeatedly tested with and without their service canines present on two tasks designed to elicit spontaneous visual attention to facial and scenic image pairs, respectively. Each stimulus contrasted an emotive image with a neutral image. A typical stimulus from the scenic task is presented on the left, below. On the right is an example facial task stimulus in data review mode showing the gaze tracks exhibited by one participant. Note the attention bias in favor of the angry expression on this occasion.



The scenic stimuli were obtained from the International Affective Picture System. Each of six equivalent forms of 64 image pairs were balanced for mean valence and arousal ratings of both aversive and pleasant images and for mean of valence difference across images using ratings provided by large undergraduate male samples. The order of image valence was randomized. Each trial began with a fixation number presented for 500 milliseconds (msec) which participants reported. Fifteen hundred msec after the offset of the fixation number, the image pair appeared for seven seconds. Participants were not further instructed. The inter-trial interval varied randomly from 500 to 1500 msec.

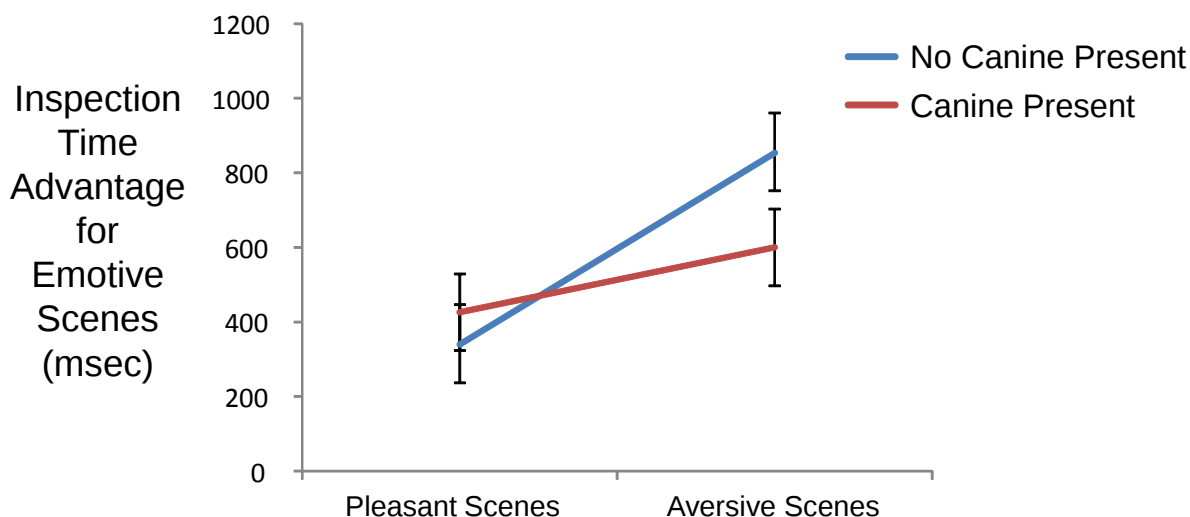
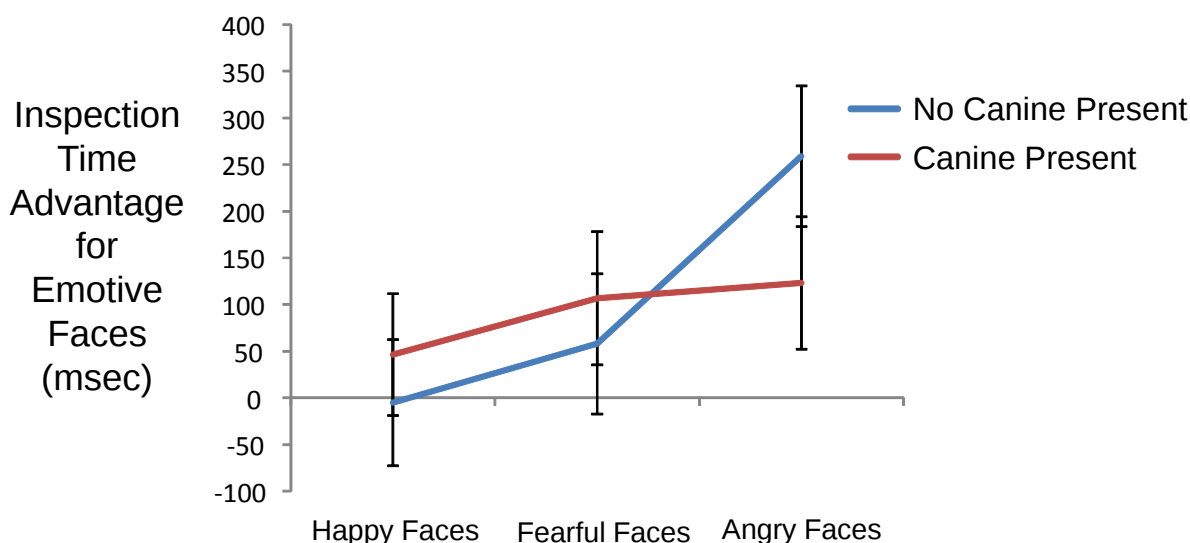
The facial stimuli were extracted from the large NimStim set. Six similar forms were developed though normative ratings are not available for the NimStim. Each set of 48 trials involved the presentation of six angry, six fearful, and twelve happy expressions, each of which was paired with either a calm or neutral expression provided by the same actor in horizontal apposition. Each pair was presented twice in alternate left-right orientations. Within each set of 48 trials, actor gender was balanced and the order of emotions randomized. Each of the forms utilized different actors. Each trial began with a single-digit fixation stimulus (“1”, “2”, or “3”) presented for 500 msec. Participants were instructed to say the number out loud. After 1500 msec, a face pair was presented for seven seconds, followed by the question “Male or female?” presented in the center of the screen for one second. Participants were instructed to vocalize the gender of the actor. The inter-trial interval varied randomly from 2 to 4.5 seconds.

The use of eye-tracking enabled relatively direct estimation of visual attention, in contrast to dot-probe methodology. The difference in visual attention directed to each image was analyzed as a function of the valence of the emotive stimulus and presence/absence of the canine. Attentional bias, operationalized as inspection time advantages for emotive vs neutral images, are plotted per task below. Figure 1 plots the least-squares means from the scenes task, and Figure 2 plots the least-squares means from the faces tasks. Apparent in both plots is the finding that across both tasks, the presence of a familiar service canine attenuated the normative attentional bias towards aversive image content. In the facial task, presence of the service canine specifically reduced attention toward angry faces.

Analyses were performed using linear mixed modeling in R.

The advantage of angry over fearful faces in recruiting attention was unexpected in light of numerous studies demonstrating that fearful faces induce amygdala activation in controls and excess amygdala activation in persons with PTSD. Studies in adults have generally not separated responses to fearful and angry faces; however, Whalen et al, in a study of eight normals, found hemodynamic responses in the amygdala to be larger in response to fearful than angry faces. In contrast, greater attentional bias to angry than fearful faces has been demonstrated in young victims of maltreatment using multiple methodologies. Contrasting responses to anger versus fear in adults with PTSD may illuminate the role of early trauma in this diagnosis.

The attenuation of attention toward social threat associated with the presence and familiarity of a service canine is compatible with reports suggesting service canines promote sociality. Also noteworthy are results indicating that human-canine interaction induces increases in circulating oxytocin, a "prosocial" hormone that also modifies fear system function in normals and in persons with PTSD. Recent studies have found that acute oxytocin reduces attentional bias towards negative facial emotion; however, such questions as whether oxytocin reduces attention to aversive content in general or to angry faces in PTSD remain to be addressed.

Figure 1**Figure 2**

What opportunities for training and professional development has the project provided?

If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. “Training” activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. “Professional development” activities

result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Nothing to report

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Woodward, S.H., Jamison, A.L., Gala, S., Holmes, T.H. Canine companionship is associated with modification of attentional bias in posttraumatic stress disorder. (Submitted)

What do you plan to do during the next reporting period to accomplish the goals?

If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

During the next reporting period, data acquisition and processing will continue as originally proposed. When and if obtained, additional positive results deemed reliable and replicable will be submitted for publication. Analyses of effects on sleep are well underway.

- 4. IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

What was the impact on the development of the principal discipline(s) of the project?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

It is still premature to attribute any changes in the practice of providing service animals to Veterans or in the conduct in animal-assisted therapy to this project.

What was the impact on other disciplines?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to report.

What was the impact on technology transfer?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to report.

What was the impact on society beyond science and technology?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to report. All findings are preliminary.

5. **CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, “Nothing to Report,” if applicable:

Changes in approach and reasons for change

Describe any changes in approach during the reporting period and reasons for these changes.

Remember that significant changes in objectives and scope require prior approval of the agency.

There are no changes in objectives or scope.

Actual or anticipated problems or delays and actions or plans to resolve them

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

As we described at the recent MOMRP review, and in communications with our past and current science officers, we have experienced significant challenges recruiting participants into the intensive limb of our study since mid-summer, 2016. There were two sources for this difficulty. One was a severe disruption of the Trauma Recovery Program occasioned largely by external forces. In brief, aggressive recruitment of VA psychiatrists by Kaiser Health led to the loss of approximately 25% of the service, hospital-wide. Compromised psychiatry staffing at the TRP necessitated a reduction in census that continues today. The current census is 16 - 20 patients. The second source of slowed recruitment was the emergence of health and behavioral issues in two of the three service dogs currently in training via the collaboration between the TRP and Paws for Purple Hearts. These issues were severe enough to preclude the 24/7 companionship or "simulated-ownership" model on which this research project was based. While it was reasonable to expect both of these dogs, given time, to come back "on-line", they have not been able to do so. The result was that only a single service dog has been available for this study over the past six months, providing only two "slots" for co-trainers. This limitation compounded the disruption in the TRP leading to the steep fall-off in recruitment.

The second of these conditions led us to engage in an ultimately productive dialogue with Paws for Purple Hearts, with the result that they will be transferring two relatively mature dogs from two of their other sites. (We will defray approximately \$1400 of their expenses incurred in this transfer.) At the same time, the TRP has re-stabilized at its new census of 16-20. In view of the continued popularity of the Service Animal Training Intervention, and the renewed availability of six co-trainer slots, we expect recruitment to return to the rates we reported in year 1.

While it may be difficult to achieve 100% of the projected total sample of 60 completers for the intensive limb of the design, we believe the study will remain robustly powered. This is because we were required, following established principles, to estimate sample sizes based on published studies. These estimates focused on the most medically consequential outcomes, baseline heart rates during waking and sleep. What we could not account for in those power estimates was the impact of the unprecedented data volumes provided by our novel technologies. That is, while the published findings regarding the impact of canine companionship on baseline heart rate were based on minutes of recording, our use of mattress actigraphy and single-patch ambulatory ECG enable us to acquire near 24-hour recordings for 20-40 days/nights. The greatly enhanced reliability of the resulting heart rate estimates should, in turn, substantially increase effective power. The early appearance of significant within-subjects effects on attentional bias and startle also leave us optimistic on this score.

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

As noted above, the resolution of the recruitment bottleneck associated with service dog availability will cost the project approximately \$1400.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

None.

Significant changes in use or care of vertebrate animals.

Not applicable.

Significant changes in use of biohazards and/or select agents

Not applicable.

6. Publications, conference papers, and presentations

Report only the major publication(s) resulting from the work under this award.

Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume; year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Woodward, S.H., Jamison, A.L., Gala, S., Holmes, T.H. Canine companionship is associated with modification of attentional bias in posttraumatic stress disorder. (Submitted)

Books or other non-periodical, one-time publications. Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: Author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).

Nothing to report.

Other publications, conference papers, and presentations. Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.

Nothing to report.

- **Website(s) or other Internet site(s)**

List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to report.

- **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. In addition to a description of the technologies or techniques, describe how they will be shared.

Nothing to report.

- **Inventions, patent applications, and/or licenses**

Identify inventions, patent applications with date, and/or licenses that have resulted from the research. State whether an application is provisional or non-provisional and indicate the application number. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to report.

- **Other Products**

Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment, and/or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- *data or databases;*
- *biospecimen collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate “no change.”

Example:

Name: Mary Smith
 Project Role: Graduate Student
 Researcher Identifier (e.g. ORCID ID): 1234567
 Nearest person month worked: 5

Contribution to Project: Ms. Smith has performed work in the area of combined error-control and constrained coding.
 Funding Support: The Ford Foundation (Complete only if the funding support is provided from other than this award).

Name: Steven Woodward
 Project Role: Principal Investigator
 Nearest person month worked: 2
 No change

Name: Andrea Jamison
 Project Role: Coordinator
 Nearest person month worked: 12
 No change.

Name: Sasha Gala
 Project Role: Research Assistant
 Nearest person month worked: 12
 No change.

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to report.

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:

Organization Name:

Location of Organization: (if foreign location list country)

Partner's contribution to the project (identify one or more)

- Financial support;
- In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);
- Facilities (e.g., project staff use the partner's facilities for project activities);
- Collaboration (e.g., partner's staff work with project staff on the project);
- Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and
- Other.

Paws for Purple Hearts

Menlo Park, California

Non-profit organization that provides and manages the service dogs, and the service animal training intervention. We have included them in this second annual report because monies were requested to defray their costs incurred in transferring two service dogs from San Diego and Virginia whose behavioral profiles are compatible with the SATI program and the original design of this project. (Two of the three PPH dogs that came into service earlier this project year proved unable to perform as needed.)

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating PI and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ers.amedd.army.mil> for each unique award.

QUAD CHARTS: If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.

9. **APPENDICES:** Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

None

Can a Canine Companion Modify Cardiac Autonomic Reactivity and Tone in PTSD

ERMS# 13046055

Award # W81XWH-15-2-0005



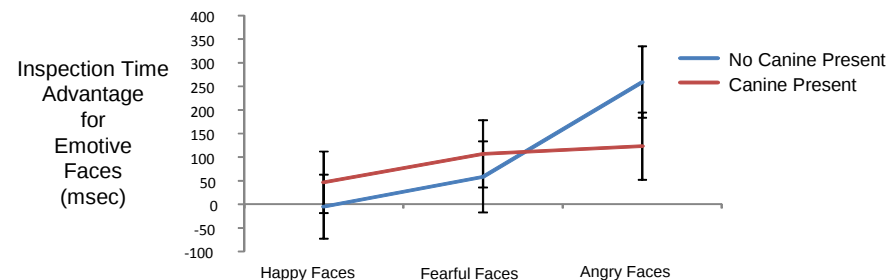
PI: Steven H. Woodward, PhD **Org:** Palo Alto Veterans Institute for Research **Award Amount:** \$1,283,573

Study/Product Aim(s)

• We propose to provide a strong test of the ability of canine-assisted therapy to mitigate recognized symptoms of PTSD that are relevant to medical and rehabilitative status. Based on studies in non-veteran, non-military samples, canine companionship may mitigate both elevated basal heart rate and poor social/interpersonal function. We will also assess the impact of canine companionship on laboratory tasks of social cognition and stress reactivity.

Approach

• We will record waking and sleeping heart rate for up to 42 days/nights in a complete sample of 60 Veterans engaged in inpatient PTSD treatment and participating in a service animal training intervention (SATI). The latter program includes extended periods both with and without the 24/7 companionship of the service animal, allowing us to use participants as their own controls. Selected between-subjects comparisons will contrast the diagnostic status' and treatment progress of SATI program participants and non-participants.



Accomplishment: Plot of the interaction of contrast and canine presence on inspection time differences favoring emotive over neutral scenes.

Timeline and Cost

Activities	FY	14	15	16	17
hiring, approvals, contracting, stim development and piloting, statistical consultation					
recruitment, structured interviewing, laboratory assessments, ambulatory psychophysiology, sleep actigraphy, preliminary data analyses, data archiving					
summary data analyses, manuscript prep & submission					
Estimated Budget (\$K) (direct)		\$317k	\$317k	\$325k	\$325k

Updated: 1/2017

Goals/Milestones (Example)

CY15 Goal – Complete startup tasks and commence recruiting

- ☒ all startup tasks completed
- ☒ 52 participants enrolled (vs 55 planned in SOW)

CY16 Goals – Continue accrual/ process data

- ☒ 110 participants enrolled, 97 completed (vs 104 planned in SOW)
- ☒ ongoing data processing/archiving/methods development

CY17 Goals – Continue accrual/ process data

- ☐ Enroll/test ~ 80 participants
- ☐ ongoing data processing/archiving/methods development

CY16 Goals – Continue accrual/ process data

- ☐ Complete enrollment/testing
- ☐ complete data analysis

Comments/Challenges/Issues/Concerns

- Modifying statistical model to accommodate additional variability in timing of canine companionship

Budget Expenditure to Date (through November, 2016)

Projected Expenditure:: \$630,415

Actual Expenditure:: \$526,070.16