Service Dog Training Program for Military Veterans With PTSD
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Protocol

This RCT will gather data from 60 veterans with Post-traumatic stress disorder (PTSD) and 30 service dogs (SDs) in training. Veterans will be recruited and screened for eligibility according to Warrior Canine Connection (WCC) inclusion criteria Humans: 1) military veteran; 2) diagnosis of PTSD; 3) able to give informed consent; and 4) able to understand English. Human Exclusion Criteria: 1) fear of dogs; 2) allergy to pet dander; 3) active substance abuse; 4) active psychosis, or 5) history of animal abuse. Dog Inclusion Criteria: 1) non-aggressive demeanor as evaluated by WCC protocols for evaluating animal temperament; 2) cleared by veterinarian; and 3) up-to date immunizations. Dog Exclusion Criteria: 1) medical holds.

Recruitment/Screening:. Recruitment will be via media attention, flyers, social media, and word of mouth.

Procedures: Veterans interested in the participating in the study will be prescreened by a research team member(RTM) for eligibility. Eligible veterans will be invited to participate. If veterans agree to participate after their questions are answered. They will be consented verbally, randomized, and scheduled for their first session with the location dependent on the arm. After informed consent is signed, baseline data will be obtained in an outdoor area at WCC [service dog training program(SDTP) arm] or at another meeting place near the participant's home [wait list control intervention((WLCI) arm].

Randomization: Participants will be block randomized, according to gender, into the SDTP or WLCI. Group assignments will be generated by a computerized random number table and envelopes will be opened after verbal informed consent. Participants will continue existing therapies and begin any for which they are referred while in the study.

Interventions:

SDTP-Intervention (human): Veterans randomized to the SDTP will be paired with an experienced WCC Mission Based Trauma Recovery (MBTR)-Trainer (MBRT-T) and a SD. One hour training modules will be scheduled once a week for 8 weeks. Participants will come to WCC for all the weekly training modules. The MBTR-T will deliver the prescribed SDTP modules created by WCC. Each session will be fully supervised by a WCC MBTR-T to address any concerns or safety issues that may arise.

Waitlist Control Intervention (WLCI): Veterans randomized to WLCI will participate in one hour online SD training modules (https://e-trainingfordogs.com) scheduled once a week for 8 weeks but not interact with service dogs. The online training modules are delivered by experienced SD trainers and will employ parallel content to the WCC SDTP. Participants will participate from their homes or at a location of their choice in online training modules.

Outcome Assessment: In both groups, human's biological [e.g. salivary and heart rate variability (HRV)] markers except telomere length (TL) will be assessed in weeks 1, 4, and 8. TL will be assessed at weeks 1 and 8. Scales for and psychosocial data will be completed prior to session 1 and after sessions 4 and 8. HRV will be recorded in the human participants during SDTP sessions and for 30 minutes after sessions.

Assessment: Human Demographics and Characteristics Questionnaire will collect demographic/descriptive data on the human participants, such as gender, age, race, ethnicity, marital status, educational level, living arrangements, military history and pet ownership history. The order of the questionnaires will be randomized to minimize order effects. A dog demographics and characteristics questionnaire will collect demographic/descriptive data including dog's name, WCC dog trainer's name, gender, age, breed, and weight. Additionally, a photo will be taken to illustrate size and face.

Aim 1 Outcome Assessment:

Primary outcome: PTSDSS will be assessed with the PTSD Checklist for DSM-5 (PCL-5), a 20-item scale.[70].[71]

Secondary outcomes:

a) Stress markers will be assessed with salivary cortisol, α- amylase, and HRV, and the perceived stress scale. Heart *rate variability* (HRV) of veterans will be measured with a Polar H7 heart rate sensor worn around the chest and matching Polar V800 GPS Sports Watch worn around a wrist to save data from the heart rate sensor and download it for analysis. Perceived stress (PS) will be assessed with the Patient-Reported Outcomes Measurement Information System (PROMIS) Perceived Stress Fixed Form v2.0 (PROMIS, PS).[72,73] and

b) Psychosocial health related to PTSD will be assessed with well validated scales, including PROMIS measures: Positive Affect-Short Form 15 (PA 15a), [75] PROMIS Satisfaction with Social Roles and Activities (SSRA) – Short Form 4a (PROMIS-SSRA),[80,81] PROMIS Short Form v1.0- Satisfaction with Participation in Discretionary Social Activities- Short Form 7a (PROMIS SPDSA), [82,83] PROMIS Companionship – Short Form 4a (PROMIS-C), [84,85] PROMIS Depression Short-Form 8a,[87] and the PROMIS Anxiety Short-Form 8a.[88] *Suicide ideation* (SI) will be assessed with the Beck Scale for Suicide Ideation.[89] Quality of life will be assessed with the Veterans RAND 12-Item Healthy Survey, [76] Resilience will be assessed with the Connor-Davidson Resilience Scale (CD-RISC-10), [78] and Quality of an individual's relationships will be assessed with the Relationship Scale Questionnaire (RSQ). [79]

c) The exploratory outcome: cellular aging will be assessed by obtaining absolute telomere length analysis.[90]

Aim 2 Outcome Assessment: Dog HRV, is a reliable measure of stress levels.[59,91] will be measured with the PetPace Collar (http://petpace.com). This non-invasive, monitor wirelessly tracks the dog's HRV and a range of physical and behavioral parameters.

Aim 3 Outcome Assessment: Participant attendance and participation in each session will be recorded by the SD trainers. The SD trainers also keep extensive notes on the interactions between the veterans and the dogs. Documentation of unintended consequences such as aggressive behavior (on either part), allergic reactions, fearful behavior (on either part). These logs will be used to assess participation in the SDTP. Exit phone interviews will be used to obtain veterans' perceptions of the SDTP and their outcomes.

Data Analysis Plan

Human Data: Before analyses, data will be cleaned and illustrated graphically. Summary statistics will be calculated, assumptions examined, and transformations applied as needed. Demographics and baseline characteristics (e.g., PTSDSS, gender) will be compared between the SDTP and WLCI groups, and the relevant variables considered as covariates for multivariable longitudinal analyses. SPSS 25 will be used for all analyses. Significance for rejecting the null is set at $p \leq .05$, Bonferonni sequential corrections will be used for multiple comparisons. The intent-to-treat approach will guide hypothesis testing. Separate sets of analyses are conducted for each outcome.

H1: Participants in the SDTP (n = 30) will demonstrate significantly greater improvement in outcomes from week 1 to weeks 4 and 8 than the WLCI (n = 30) in: a) PTSD symptom severity; b) stress markers (decreased cortisol, α-amylase, perceived stress; increased IgA, HRV); c) psychosocial health (increased positive affect, QOL, resilience, and relationships with friends and family, satisfaction with social activities and roles, companionship and decreased depression, anxiety, and suicide ideation); and d) exploratory stress marker cellular aging [increased TL, from weeks 1 to 8 only).

Linear mixed models (LMMs) with random intercepts (participant as a random variable) will be used to assess differences in changes in each outcome between the SDTP and WLCI participants, accounting for the correlation with the repeated measurements of each participant, and using all available data. Fixed effects will include group (SDTP or WLCI), week (1, 4 and 8), and their interaction, as well as the relevant covariates. The hypothesized effect of the intervention will be tested with the week by group interaction. Interactions of covariates (e.g. gender and age) with the group and time will be explored to provide information about their influence and for preliminary data to justify formal evaluation (with adequate power) in future studies. The multi-modal assessment in this study will provide the opportunity to explore characteristics that predict benefits.

Dog data: For analyses of data from dogs, demographics and baseline characteristics (e.g., size, gender, age), will be computed. The distributional characteristics of HRV (e.g., normality, outliers and missing) will be explored. Appropriate steps will be used as needed to ensure that applicable assumptions are met. Descriptive statistics will be computed for HRV by week and period (pre, during, and post).

H2: Dogs who participate in the SDTP will not experience increases in stress (decreases in HRV) from the 30 minutes before, to during, and after SDTP sessions. LMMs with random intercepts (dog as a random variable)

will be used to assess the significance of changes between the three periods, accounting for the correlation within the repeated measurements. Fixed effects will include period [pre, during, post SDTP session] and week (1, 4, 8). The hypothesized effect of the SDTP will be tested by evaluating the contribution of period to HRV. Interactions of dog covariates (e.g., dog gender and age) with period will explored to evaluate their potential influence and for exploring a need for evaluation of their roles.

H3: Dogs who participate in the SDTP will not experience increases in stress (decreases in HRV) over 8 weeks of the SDTP. The hypothesized effect of the intervention will be tested by evaluating contribution of week to HRV based on the LMM used for aim 2. Interactions of dog covariates (e.g. gender, age) with week will be explored to provide information about their potential influence to inform development of future studies.

Feasibility data: Descriptive statistics will be calculated for number of sessions attended, rates of completion, drop out adverse events, and follow up questions, etc. Effect size estimates will be calculated for each veteran outcome and for dog HRV. They will enhance sample size calculations for a future multi-program RTC.

Missing Data. While complete data are ideal and we will make considerable effort to obtain them, some missingness is likely. Randomness of missingness will be tested. If there is excessive or differential attrition across groups or informative missingness, we will apply sensitivity analysis, such as pattern mixture models for longitudinal data.[92] If the results differ, we will report both.

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