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The Economic Impact and Cost Effectiveness of Service Dogs for Veterans with Post Traumatic Stress Disorder

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For a complete list of stakeholders from whom we requested input, please visit: https://icer.org/assessment/ptsd-service-dogs-2021/

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Preface

In 2014, the U.S. Department of Veterans Affairs (VA) began the first randomized controlled trial to evaluate whether service dogs could provide therapeutic and economics benefits for Veterans with post-traumatic stress disorder (PTSD). The study evaluated whether receipt of a service dog, compared to an emotional support dog, improved overall functioning and quality of life, and the impact on mental health outcomes, health care utilization and costs, and employment and productivity. VA contracted with the Institute for Clinical and Economic Review (ICER) to evaluate the cost-effectiveness of this intervention. The first monograph evaluated the pairing of Veterans with PTSD with service dogs versus emotional support dogs in terms of their effect on disability, quality of life and PTSD-related symptoms. Here, in the second monograph, we present results from the trial's health economic analysis (Chapter 1) and a modeled cost-effectiveness analysis (Chapter 2).

Chapter 1 reviews the health economic outcomes of the trial, including health care costs, utilization, work productivity and employment during the 18 months after a participant was paired with a dog. Participants who received a service dog were not significantly different than participants who received an emotional support dog in total health care costs in the 18 months after being paired with a dog. The findings also provided no evidence that a service dog would reduce mental health utilization and costs when compared to an emotional support dog. An analysis of medication adherence, using proportion days covered (PDC), indicated that participants randomized to the service dog intervention group experienced a 10-percentage point (SE 0.03, $p<0.01$) greater use of antidepressants.

Seven economic outcomes, including employment and work productivity, were collected through self-report. Participants experienced no significant differences in 6 of the 7 measures of employment and work productivity, with the exception of the impact of health on work productivity over time. The service dog group reported that their health had a greater impact on work productivity than the emotional support group by 18 months (beta = 2.25; 95% CI 0.39, 4.11; $p<0.05$). The self-reported economic outcomes provided no evidence that service dogs positively impacted employment and work productivity, although the estimates were often not precise, likely due to the small sample sizes.

Chapter 2 presents the results of the cost-effectiveness analysis. Using a decision-analytic model, this analysis evaluates the cost-effectiveness of receiving a service dog for Veterans with PTSD at the prices paid within the clinical trial. The primary analysis compared the effect of a service dog to that of an emotional support dog. It assumed a perspective of a comprehensive health system payer responsible for paying all costs related to procurement, pairing, and insurance for these dogs. In addition to standard sensitivity analyses, the team conducted twothreshold analyses: 1. assuming a societal perspective and solving for the number of increased work hours per week that Veterans

receiving a service dog would be needed to meet common cost-effectiveness thresholds and; 2. assuming only the insurance costs of the service dog and solving for the health benefits needed to meet common cost-effectiveness thresholds when comparing the service dog intervention to no dog.

The comprehensive health system payer perspective indicates that the service dog intervention would require a cost reduction of 14% -- from $42,478 to $36,498 -- to meet a commonly cited cost-effectiveness threshold of $100,000 per quality-adjusted life year (QALY) gained. The societal perspective threshold analysis suggests favorable cost-effectiveness findings for service dogs if cost savings can be demonstrated by small increases in Veteran weekly work hours when compared to emotional support dogs. The threshold analysis comparing service dogs to no dog suggests health gain targets for future studies to achieve favorable cost-effectiveness findings.

This is the first study looking at the effect of providing a service dog to Veterans with PTSD on health care cost and utilization, and the cost-effectiveness of this intervention. There are limitations to these results. The health economic analyses included only participants who were randomized and paired with a dog; therefore, it may not be an unbiased causal estimate. Findings from the cost-effectiveness analysis are subject to uncertainty and cost-effectiveness is but one element that decision-makers should consider in a broader judgment of value.

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List of Acronyms and Abbreviations

ADA	Americans with Disabilities Act
ADI	Assistance Dogs International
AKC	American Kennel Club
AHRQ	Agency for Healthcare Research and Quality
ASCVD	Atherosclerotic Cardiovascular Disease
C-SSRS	Columbia-Suicide Severity Rating Scale
DSM-5	Diagnostic and Statistical Manual of Mental Disorders, 5th Edition
EMOT	Emotional support dog (used interchangeably through monograph)
evLYG	Equal Value of Life Years Gained
FDA	US Food and Drug Administration
GEE	Generalized Estimating Equation
IRB	Institutional Review Board
MI	Myocardial infarction
PDC	Proportion of Days Covered
PCL-4	PTSD Civilian Checklist 4
PCL-5	PTSD Civilian Checklist 5
PHQ-9	Patient Health Questionnaire 9
PSQI	Pittsburgh Sleep Quality Index
PTSD	Post-traumatic stress disorder
QALY	Quality-Adjusted Life Year
SERV	Service dog (used interchangeably through monograph)
US	United States
VA	United States Department of Veterans Affairs
VR-12	Veterans RAND 12-Item Health Survey
VSO	Veteran Service Organization
WHO-DAS 2.0	World Health Organization Disability Assessment Scale II

Chapter 1

The Economic Impact of Service Dogs for Veterans with Post Traumatic Stress Disorder

1. Abstract

Anecdotal stories and media reports suggest that service dogs can provide mental health and economic benefits to individuals with post-traumatic stress disorder (PTSD). Following the 2010 National Defense Authorization Act (Section 1077), VA conducted the first randomized clinical trial to evaluate whether service dogs (trained in obedience and mental health specific tasks) could mitigate the symptoms of PTSD and provide any economic benefits or savings to the health care system relative to emotional support dogs. A prior report examined the effects of service dogs on PTSD symptoms and well-being.[1] This report presents the trial's health economic results.

The analysis examines health care cost and utilization as well as work productivity and employment. We used VA administrative and patient self-reported data to examine outcomes 18 months post-pairing. The primary analysis compared outcomes for participants who received a service dog (SERV) versus those who received an emotional support dog (EMOT).

Participants who received the SERV intervention were not significantly different than participants who received the EMOT intervention in total health care costs. We also found no significant differences in more specific measures of health care utilization or costs. In totality, we found no evidence that the SERV intervention would reduce utilization and costs when compared to the EMOT intervention. Some results indicated that the SERV intervention increased mental health utilization and costs, although these findings were not consistent across statistical models or follow-up time periods. An analysis of medication adherence, using proportion days covered (PDC), indicated that participants randomized to the SERV intervention experienced a 10-percentage point (SE 0.03, $p<0.01$) increase in their PDC for antidepressants, and a trend towards lower PDC in benzodiazepines (-7 percentage points) and other sedatives/hypnotics (-8 percentage points); however, the effects on benzodiazepines and other sedatives/hypnotics were not significant. An exploratory analysis comparing low versus high PTSD symptoms, as measured with the PTSD Civilian Checklist-5 (PCL-5) at baseline, showed no significant differences for any outcomes.

Veterans paired with a service dog experienced no significant differences in six of the seven measures of employment and work productivity collected through self-report. One exception was the impact of health on work productivity over time; the service dog group reported that their health had a higher impact on work productivity than the emotional support group by 18 months (beta = 2.25; 95% CI 0.39, 4.11; $p<0.05$).

This is the first study analyzing the effect of providing a SERV to Veterans with PTSD on health care cost and utilization. Receipt of a SERV did not significantly reduce VA utilization or cost when compared to receipt of an EMOT. Receipt of a SERV improved proportion of days covered for antidepressant medications. However, receipt of a SERV did not improve Veterans' ability to maintain their regular daily activities. Results from this study are subject to limitations. The primary analysis includes only participants wo were paired with a dog; therefore, it may not be an unbiased

causal estimate. Results from secondary analysis using multiple imputation with the full sample of randomized participants yielded similar results, but this is an important limitation. A separate cost-effectiveness analysis reported in chapter 2 synthesizes these results for decision makers.

1.1. Introduction

One third of Veterans who served in Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF) have been diagnosed with Post-Traumatic Stress Disorder (PTSD), traumatic brain injury, and/or depression.[2] Between fiscal years (FY) 2002 and 2015, the number of Veterans diagnosed with PTSD was approximately 400,000.[3] In 2012, VA spent over $3 billion providing PTSD care for Veterans.[4] The cost of VA health care per year for a Veteran with PTSD was more than twice as much the cost of care for a Veteran without PTSD.[5]

People with PTSD often relive the triggering event; they may avoid situations that set off painful memories and may be on the lookout for danger.[6] A variety of mental health issues are often comorbid with PTSD including major depressive disorder, anxiety disorders, eating disorders, substance use disorders, and suicide, as well as increased risk for dementia and overall mortality.[7–13] The rate for completed suicide in 2017 for Veterans was 50% higher than that of the non-Veteran adult population.[14]

Veterans have higher rates of unemployment than non-Veterans due to physical and mental injuries from military service.[15] PTSD has been shown to decrease the likelihood of gainful employment;[16] years of education have less of an effect on unemployment than PTSD status.[17] A 2008 study reported that at discharge from military service, Veterans with PTSD were 19% less likely to be employed than Veterans without a PTSD diagnosis.[18]

The use of animals as a therapeutic intervention (i.e. animal-assisted therapy) typically supplements traditional evidence-based mental health treatments.[19] Owning a pet, primarily dogs and cats, has been associated with positive health effects. An Australian National Survey conducted by Headey and colleagues[20] found that individuals who owned a dog or cat, as compared to non-pet owners, made fewer visits to their doctor and were less likely to take medication for heart or sleep disorders. In a survey of German and Australian citizens, Headey and Grabka[21] reported that pet owners visited their physicians approximately 15% less than non-pet owners, after controlling for gender, age, marital status, income, and other health variables.

Service dogs differ from emotional support dogs, which are pets, because they are trained to perform one or more tasks for people with disabilities that are directly related to the person's disability.[2] In contrast, an emotional support dog may be trained in obedience at the owner's discretion but is not trained to perform a task to mitigate a disability.[2] There is some limited evidence indicating that service dogs can have a positive impact on economic outcomes. Wirth and Rein[22] observed gains in productivity in some individuals with a guide dog because their dogs helped them become more mobile and socially interactive, which led to an increase in employment. In a non-randomized study that examined the effect of usual care versus usual care plus a service dog in 141 military members and Veterans with PTSD, O'Haire and Rodriguez[23] found that the service dog group had lower absenteeism due to health among the employed participants;

however, there were no differences in employment status. Employment provides Veterans a sense of independence, satisfaction, as well as an opportunity to interact with their co-workers; Veterans who form social bonds were more likely to have a remission of PTSD.[24] Employment may also play a role in improving mental health and maintaining abstinence from alcohol and drug abuse in persons with PTSD.[24]

The research to date has been largely correlational and some have questioned the causal effects that animals can have on human health, well-being, and employment.[25] Experts have advocated for more research on the causal link between PTSD treatment and economic endpoints.[16,17,26] Section 1077 of the National Defense Authorization Act of 2010 stipulated that the VA examine the impact of service dogs on disability, quality of life, and PTSD-related symptoms in Veterans with PTSD. Section 1077 also required an economic evaluation, such as the effect on hospitalizations and prescription drug use, as well as productivity and employment.

We sought to understand the effects of providing a service dog trained specifically to address PTSD disabilities on health care cost and utilization as well as work productivity and employment for Veterans with PTSD. We compared outcomes for Veterans who received a service dog to Veterans who received an emotional support dog.

Service dogs and emotional support dogs used in practice (the real world) may be obtained from breeders or random sources (i.e. animal shelters, rescue organizations, donated dogs, etc.). These two dog types differ in the ability of service dogs to remain calm, confident, and focused while performing skilled tasks to mitigate the handler's disability a in a wide variety of public settings. Dogs that display fear (of strangers, crowds, certain public settings such as elevators, revolving doors, etc.) and/or are easily distracted create a management and/or a safety issue for their handlers. Good-natured dogs that lack the focus and confidence of service dogs are best suited to the role of an emotional support dog, which live in the home and accompany their handlers in dog-friendly community environments.

For the study, VA intentionally used dogs with a known pedigree as opposed to random-source dogs. Labrador Retriever-Golden Retriever crosses, Labrador Retrievers, and German Shepherds are the most commonly used breeds by Assistance Dogs International (ADI) and International Guide Dog Federation (IGDF) organizations because of their intelligence, trainability, and temperament;[27] therefore, these were the breeds used in the study. All dogs (i.e. service dogs or emotional support dogs) paired with study Veterans were trained in obedience because VA placed a high priority on the safety of Veterans and their families, especially children who visited or lived in the Veterans' homes. VA consulted subject matter experts in the field of canine training and developed the training standards for the study. Detailed information regarding the procurement, medical evaluation, training requirements (obedience, public access, and service dog skilled tasks), and placement procedures of the study dogs with participants as well as the clinical and therapeutic outcomes of the study were reported in a separate monograph, hereafter referred to as the first

monograph.[1] The potential impact of VA's training standards on the generalizability of the study is discussed on pages 42-43.

1.2. Methods

1.2.1. Study population

This economic analysis was conducted alongside a multisite, randomized controlled trial (ClinicalTrials.gov NCT02039843). The trial enrolled Veterans age 18 or older with a diagnosis of PTSD. Participants were eligible if they received VA mental health care and had attended at least one mental health visit within 90 days prior to consent. Participants agreed to remain in mental health treatment throughout the study and were able to adequately care for a dog. The full eligibility requirements are available in the first monograph.[1]

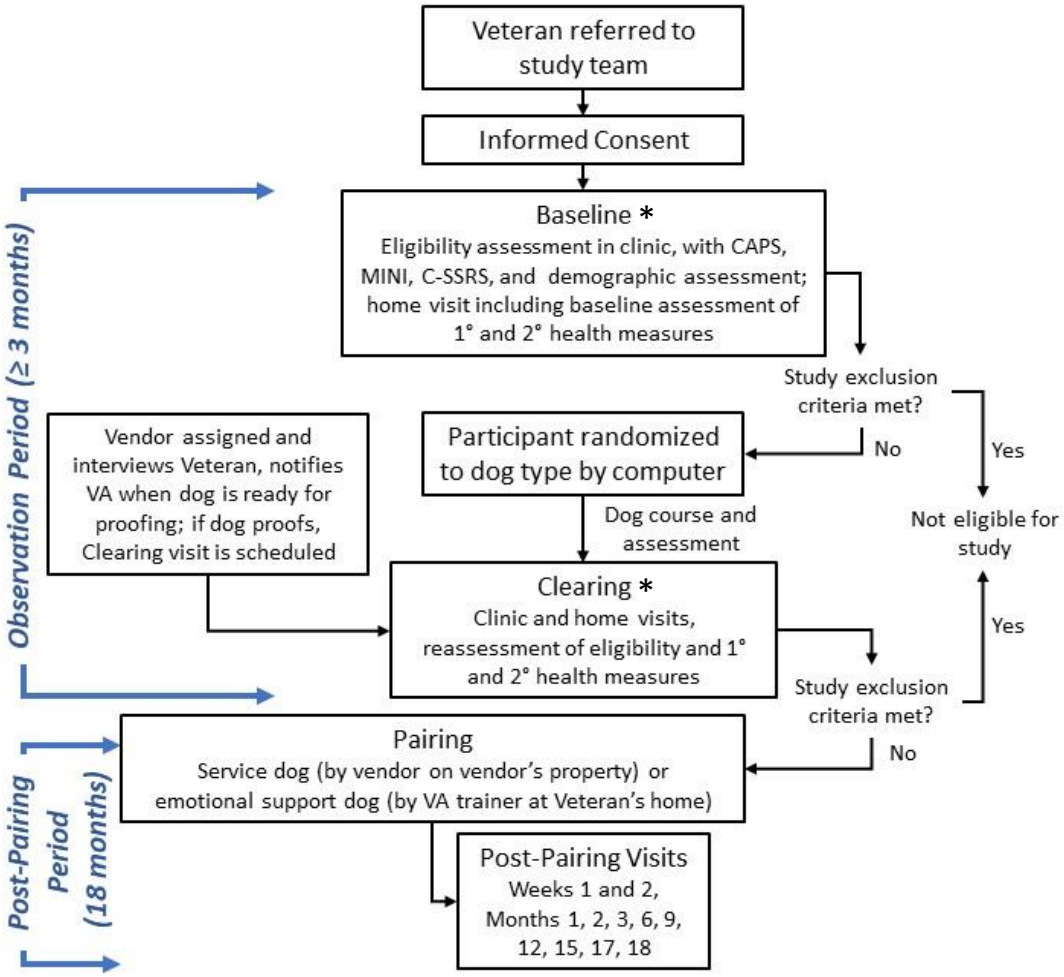
Participants were screened, consented, and enrolled from three VA Medical Centers from December 2014 through June 2017. Participants were randomized 1:1 to a service dog (SERV) intervention or an emotional support dog (EMOT) intervention by the study coordinating center using the computer-generated Interactive Touch Tone Randomization System (ITTRS). Participants provided baseline information on questionnaires at the time of randomization and then again at the time they were paired with a dog. Once randomization occurred, participants were observed for at least three months. During the observation period, neither the local study team nor the participants knew the type of dog to which the Veteran had been assigned; this measure was taken to reduce bias. The participant and the local study team learned the dog type assignment when the observation period was completed; the revealing of the dog type occurred at the home clearing visit. The average time from randomization to pairing was 158 day for both study groups.

After being paired with either a service dog or emotional support dog, participants were followed for 18 months. Follow-up assessments were performed at clinic or home visits as shown in Figures 1.1 (basic study flow) and 1.2 (assessment schedule). A total of 181 participants were paired with dogs: 97 in the service dog group and 84 in the emotional support dog group. The final 18-month follow-up period ended June 2019. Outcome data were obtained through participant self-report and VA administrative data. Administrative data was complete for all participants; at the 18-month follow-up period, 88 participants in the service dog group and 65 participants in the emotional support dog group completed the final self-report assessment.

The clinical trial was designed based on two primary outcomes: the World Health Organization Disability Assessment Scale II (WHO-DAS 2.0) and the Veterans Rand 12 Item Health Survey (VR-12), which includes physical and mental component subscales. Chapter 2 provides more information on the study's clinical measures and outcomes described in the first monograph. The study was

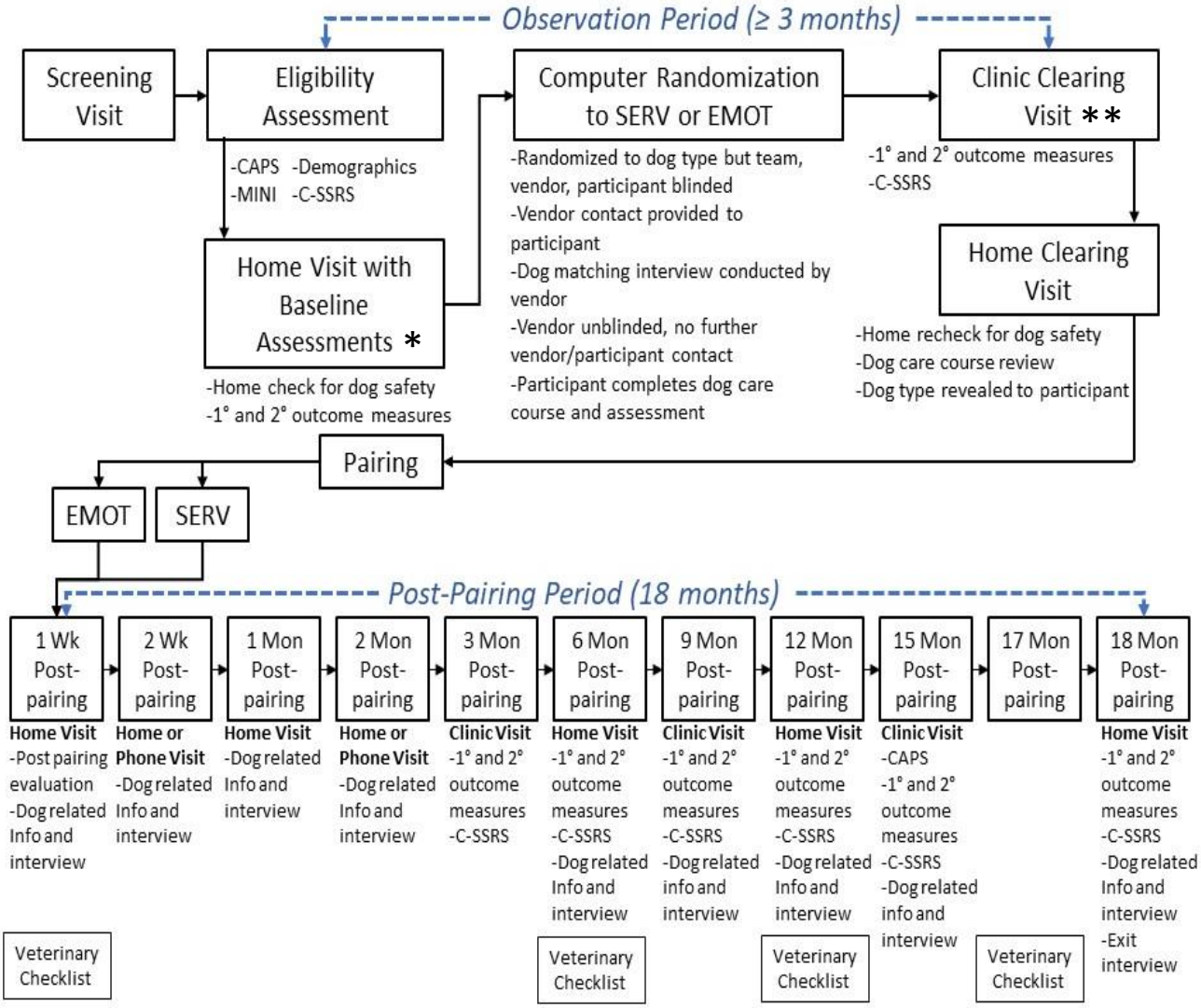
powered to detect a 15% difference in mean scores for VR-12 mental component scale (outcome requiring largest sample) over 18 months of follow-up, at a statistical significance level of 0.05 (two-tailed test) and a power of 85%. The study sought to enroll 110 participants per group (220 total), assuming a 25% post-pairing dropout rate for a total of 82 participants per treatment group.[28]

Figure 1.1. Study Flow



Source: Saunders, et al.[28]
* Also referred to as "Baseline 1 testing occurring during home visit"
** Also referred to as "Baseline 2 assessments"

Figure 1.2. Study design including assessments



Source: Saunders, et al.[28]
* Also referred to as "Baseline 1 testing occurring during home visit"
** Also referred to as "Baseline 2 assessments"

1.2.2. Randomization

The protocol specified two dates: the date of randomization and the date of pairing with a dog. The protocol defined intent to treat (ITT) based on the randomization date and per-protocol based on the pairing date.

An ITT analysis based on complete case data from the VA administrative files was not possible. Of the 227 randomized participants, 46 withdrew prior to pairing, with a greater percentage withdrawing from the EMOT arm than the SERV group (29 in the EMOT group and 17 in the SERV group). According to the VA Privacy Office and Central Institutional Review Board (IRB), once a Veteran withdrew from the study, we could no longer use any protected health information or administrative data for these 46 individuals. This left us with two options.

1. An analysis of all 227 randomized participants, using multiple imputation for the 46 people who withdrew from the trial

2. Complete case analysis for the 181 participants who were paired with a dog

Option 1, multiple imputation based on the randomization date, involved imputing all data for the 46 participants who were randomized but not paired. Although multiple imputation is widely used for missing data, this method may not be preferred to a complete case analysis when data are not missing completely at random.[29,30] Given the evidence that missingness was not missing at random,[1] we conducted a complete case analysis. However, we present the results from multiple imputation in section 1.3.7. so that readers may compare these results to the complete case analysis.

Our remaining question was whether to use the pairing date or the randomization date. The VA administrative data could be analyzed using the randomization or pairing date. However, all self-report assessments were based on the pairing date. Thus, a complete case analysis based on the randomization date would disconnect the administrative and self-report outcomes. In contrast, if we used the pairing date, then we could align the timing of administrative and self-reported outcomes. In conclusion, we believed the pairing date provided the most accurate, useful, and unbiased information for the analysis.

Therefore, the primary results in this monograph report the complete case analysis with the paring date. This is referred to as the per-protocol analysis, as described in the protocol. The per-protocol population maintains the randomization structure but excludes individuals who were never paired with a dog.

The main scientific concern with the per-protocol analysis is the threat to the internal validity. Because the sample includes people who were randomized and paired, it may not be an unbiased causal estimate.

1.2.3. Data

Administrative Data

We used VA administrative data to identify VA utilization and cost information for the study participants. We identified inpatient, outpatient, and pharmacy utilization and costs using the Managerial Cost Accounting inpatient treating specialty and outpatient files.[31] Medication information was extracted from the Managerial Cost Accounting Pharmacy file. The Managerial Cost Accounting datasets use activity-based cost methods to estimate the cost of producing care. These methods are precise and considered the gold standard for health economic evaluations.[32]

Cost and utilization data were grouped into mutually exclusive categories of care using Inpatient Treating Specialty or Outpatient Clinic Stop codes. We included the following categories: Inpatient Medical/Surgical, Inpatient Psychiatry/Mental Health, Inpatient Substance Use Treatment, Inpatient Other, Outpatient Medical/Surgical, Outpatient Pharmacy, Outpatient Psychiatry/Mental Health, Outpatient Substance Use Treatment, and Outpatient Other (see Supplement 4 for a complete list of codes).

We included all VA cost and utilization data for the 540 days (i.e., 18 months) before pairing date and 540 days starting on the date of pairing for each participant. We summarized the data into 12 90-day periods (6 pre-pairing periods and 6 post-pairing periods). For each 90-day period, we summed the number of admissions and inpatient days, number of unique days with an outpatient visit, and total costs. We created subtotals of admissions, inpatient days, and costs for inpatient categories of care, and number of unique days and costs for outpatient categories of care. If a participant did not use VA health care in the 90-day period, the values were set to zero. One participant died during the study, and this participant's data was set to missing in the period after death. All costs were adjusted using the annual Consumer Price Index for All Urban Consumers (CPI-U) for 2018.

We calculated Proportion of Days Covered (PDC) to measure medication adherence for common psychiatric medications dispensed by VA. PDC has been endorsed by the National Quality Forum and the Pharmacy Quality Alliance, and it is widely used in research.[33–35] PDC is the number of days supplied for a prescription during the observation period divided by the number of days in the observation period. The maximum value PDC was one, and this value was multiplied by 100 to obtain a percent .[36] Using the VA Drug Class variable, we categorized medications into four categories: antidepressants (CN600-CN699), antipsychotics (CN700-CN799), benzodiazepine (CN302), and other hypnotics and sedatives (CN300, CN301, CN309). Proportions were computed by drug class. PDC was only computed for participants with at least one refill in the drug class. Raebel and colleagues[36] refer to this as secondary adherence, and this method is consistent with methods for calculating PDC used by Pharmacy Quality Alliance[37] and National Quality Forum.[38] The computation of PDC was done separately for the 18 months prior to pairing and the 18 months

post-pairing. The PDC starts on the day the prescription was dispensed and then was only computed for prescriptions with a refill in the time period. It was possible for a person to have a PDC in one time period, but not in the other (i.e., an unbalanced panel).

Self-Report Measures

Self-report data were collected during interviews at baseline, when participants were cleared to receive dog, and at 3, 6, 9, 12, 15, and 18 months after pairing with a dog (see Figure 1.2). Participants were asked about non-VA outpatient, inpatient, and emergency department visits during the prior 3 months. To combine the non-VA utilization with the VA costs, we converted non-VA utilization into costs with the following cost estimates based on VA data: $18,882 per inpatient stay, $283 per visit for outpatient care, and $392 per visit for emergency care. Cost estimates were based on average costs from VA data in 2019. Participants were also asked to log all non-VA medications and sleep aids, including over the counter medications, used throughout the study.

Work productivity and employment was recorded using the 6-item Work Productivity and Activity Impairment Questionnaire: General Health Problem V2.0 (WPAI). This measure was completed at baseline, when the participant was cleared to receive dog, and at 3, 6, 9, 12, 15, and 18 months after pairing with a dog. The WPAI documents work missed due to health and other problems, as well as the effect of the health problems on productivity while at work. WPAI outcomes are expressed as impairment percentages, with higher numbers indicating greater impairment and less productivity.

The self-report data were collected as close to the timing of follow-up assessments as possible. Including follow-up data and assigning it to a follow-up period was based on ranges, as specified in the protocol.

1.2.4. Analysis

The primary outcome was the total health care costs. This was estimated from the administrative data for VA utilization and self-report for non-VA utilization. We examined heterogenous response by examining subtotals based on the type of care as reported in the VA administrative data. We followed the analysis plan as specified in the protocol. We compared the cost and utilization data across the treatment arms in unadjusted bivariate analysis. The protocol specified statistical controls for gender and enrollment site, so these are included in all regression models. The protocol did not include any adjustment for multiple comparisons, so we use an alpha threshold of 5% (two tailed test) for all analyses. All analyses were performed in SAS 9.2 and Stata 16. This study was approved by the Stanford University IRB.

VA Utilization and Cost

We used multivariate panel models to examine whether treatment assignment was associated with VA utilization and costs. In these models, we included the time periods after pairing and accounted for repeated observation per participant using a random effect. In addition to the main effect for treatment assignment, we included gender, site dummy variables to control for site effects including geographic variation in costs, and dummy variables for the follow-up periods.

To evaluate the main effect of the SERV intervention on VA utilization, we used negative binomial regression. Because the negative binomial regression did not converge for outpatient pharmacy utilization, we used a Poisson regression. We considered linear and general estimating equations (GEE) models with a log link and a gamma error distribution for the cost data; we chose the linear model because the modified Hosmer-Lemeshow[39] statistic indicated that the linear model fit the distribution of the cost data better than the GEE model; we report GEE models in sensitivity analyses.

The models described above estimate an average treatment effect across the follow-up periods. To determine if the effect of the SERV intervention varied over time, we ran regression models where we included an interaction between treatment assignment and the follow-up time periods. For this interaction effect, we ran models where time was a linear effect as well as models where time was a set of dummy variables to allow for non-linear effects.

VA Prescription Drug Use

We analyzed the effect of the SERV intervention on PDC using a linear model in which we compare treatment groups. In these panel data models, we included a person random effect and we controlled for PDC prior to pairing because this improves efficiency in the estimator.[40]

Self-Reported Use of Non-VA Care

We tabulated self-reported VA reliance and use of non-VA inpatient care, outpatient care, and emergency care for each follow-up period. Each person could contribute up to 6 observations, and we included a person-level random effect to account for the non-independence in follow-up assessments. We also tabulated self-reported non-VA medications. In these panel data models, we included a person random effect and we controlled for baseline levels of the dependent variable to improve efficiency of the estimator.[40]

Self-Reported Work Productivity

In the work productivity analysis, we analyzed only participants who were employed. One question asked about actual hours worked in the past 7 days. Among employed participants, the median

number of hours worked was 32. The majority (77%) reported working 40 hours or less, but there were a number of participants who reported working more than 40 hours. 10% reported working more than 50 hours, and 6 percent reported working more than 60 hours with the maximum being 99. For the main analysis, we capped reported hours worked at 50, but in a sensitivity analysis we use actual reported hours worked.

The WPAI questionnaire also tracks the effect of health on non-work activities using an 11-point scale (0-10), with a high score represents a worse outcome. Per the scoring manual, we also created an overall productivity impact score, which was computed using the impact of health problems on work productivity if the participant was formally employed and impact of health problems on productivity for activities of daily living if the participant was not formally employed.

For the employment models, we used a logit to model the probability of being employed. We used a linear model to examine the average number of hours worked in the past seven days. In the panel data models, we included a person random effect and we controlled for baseline values of the dependent variable because this improves efficiency in the estimator.[40]

Attrition and Intent to Treat

Not all participants who were randomized were paired with a dog, and attrition was unbalanced between the study arms (see section 1.3 for more information). Therefore, we present baseline information for four groups: participants who were randomized to receive a service dog group but never paired, participants who were randomized to receive an emotional support dog but never paired, participants who were paired with a service dog, and participants who were paired with an emotional support dog.

The main results were calculated using a per protocol analysis due to concerns of biased estimates resulting from multiple imputation (see section 1.2.2 for more details). However, we conducted additional analyses to examine the possible effect of those who withdrew from the study. First, we used multiple imputation for the 46 people who withdrew from the trial. We computed 10 replicant datasets using monotonic chained equations.

Second, we estimated the probability of being paired with a dog, conditional on baseline information. We examined the common support across the two groups; two people shared no common support with those who dropped out of the study. We used the probability as an inverse probability weight in analyses. In addition, we also ran the weighted analyses excluding the 2 paired individuals who did not share any common support.

Sensitivity analysis

Statistical Models

We examined three alternative statistical models with the VA administrative data. First, we used a GEE regression with a log link and a gamma error distribution. The link function and error distribution were guided by a Box-Cox and modified Park test.[41–43] Second, we also used a person fixed effect instead of a person random effect. This fixed-effect model can only be estimated when the fixed effect is allowed to vary over the follow-up periods. Third, we included follow-up time as a linear parameter, rather than dummy variables. The gain in efficiency is due to an assumption of a linear time trend.

We conducted a subgroup analysis evaluating all VA cost and utilization outcomes based on the severity of PTSD symptoms at baseline, measured by the PTSD Civilian Checklist-5 (PCL-5). PCL-5 is a self-report measure that assesses the 20 symptoms of PTSD included in the Diagnostic and Statistical Manual of Mental Disorder, fifth edition (DSM-5). Scores can range from 0 to 80, with higher scores representing greater symptom severity. PCL-5 was collected by the study team as a secondary outcome in the clinical trial. Here, we divided the group into low and high PCL-5 based on a median split of PCL-5 at Baseline (high >=50; low <50).

Multiple Imputation for Self-Report Data

The VA administrative data provided complete information on VA health care costs and utilization. However, the self-report was subject to missing data. Missing data was significantly higher in the EMOT group than in the SERV group. At month 3, 9.5% of those participants in the EMOT group did not complete the questions on non-VA use or work productivity while only 2.1% did not complete these forms in the service dog SERV group. By month 18, 22.6% and 9.3% did not complete these forms in the EMOT and SERV groups, respectively. Loss to follow-up could bias the results and affect the statistical precision. To examine selective attrition, we used logistic regression to examine the odds of attrition (being lost) based on baseline data. Table 1.1 shows the correlates of being lost to follow-up. Being in the EMOT group was significantly associated with attrition (adjusted odds ratio 0.36, 95% CI 0.14-0.90). Outpatient reliance and being employed had large odds, but neither was significantly below an alpha of 0.05.

Our primary models were based on the complete case analysis because the missing data were not missing completely at random. It is possible that the treatment resulted in more complete follow up data. In this case, multiple imputation can induce bias.[29,30] In sensitivity analyses we used multiple imputation for the missing data due to loss to follow-up. We transposed the analytical dataset into a wide format in which each observation was a person. We used chained monotonic multiple imputation models in which data from prior follow-up assessments could be used in the

imputations. We created 10 replicant datasets, re-transformed the data to a long format, and then used standard analytical approaches in Stata 16 for combining results across the replicant datasets.

Table 1.1. Loss to Follow-up (n=179)

	Odds Ratio	95% CI		p-value
Service Dog Group vs Emotional Support Dog Group	0.36	0.14	0.90	0.029
Baseline scores				
WHO DAS Score	1.01	0.98	1.03	0.699
Health impacts productivity	0.79	0.58	1.10	0.161
Employed	1.69	0.68	4.19	0.256
Health impacts regular Activities	1.16	0.84	1.61	0.369
Outpatient VA reliance	1.52	0.96	2.40	0.076
Inpatient VA reliance	0.88	0.42	1.82	0.725

Unit Costs for Self-Reported Health Care Utilization

We converted non-VA self-reported utilization to costs based on average VA costs as reported in the Managerial Cost Accounting data. In sensitivity analyses, we varied the average cost parameters based on data from the Healthcare Cost and Utilization Project databases. The results were highly robust and so we reported the estimates based on VA costs.

Exploratory Pre-Post Analysis

In exploratory analyses, we conducted an observational pre-post analysis of outcomes. We compared outcomes for all participants in the 18 months prior to pairing (pre) and after they received a dog (post) for VA costs and utilization. The results from the pre-post analysis are presented in Supplement 3. These results should be interpreted with caution because they could be confounded by trends over time.

1.3. Results

1.3.1. Baseline Characteristics

A total of 181 Veterans out of 227 randomized were paired with a dog (97 SERV and 84 EMOT). (Figure 1.3). Forty-six participants withdrew prior to pairing, with a greater percentage withdrawing from the EMOT arm than the SERV group (29 in the EMOT group and 17 in the SERV group). The most common reasons for withdrawal before pairing included moving out of the area (EMOT=5; SERV=5), unwillingness to accept randomization assignment (EMOT=6. SERV=1), unable to locate

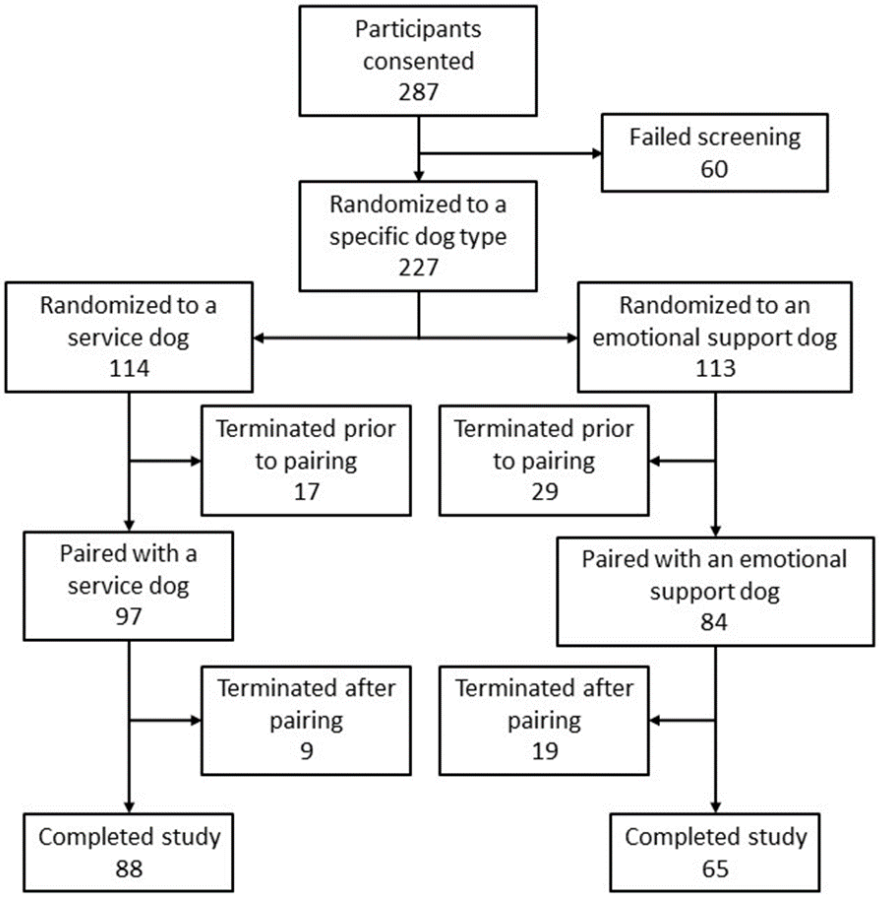
participant (EMOT=2, SERV=3), and the family decided to withdraw (EMOT=2, SERV=3).[1] Attrition post pairing was also greater for the EMOT group (19 in the EMOT group and 9 in the SERV group). The most common reasons were the family decided to withdraw (EMOT=4, SERV=1), the participant could not be located (EMOT=1, SERV=4), and the participant was not able to care for the dog (EMOT=3, SERV=0).[1] A detailed description of the reasons for participant withdrawal is available in the monograph by Richerson et al.[1] Results are presented for the per-protocol cohort of participants who were paired with a dog.

Participants were on average 50.6 years old (SD=13.6; range 22-79), and the majority were male (80.1%), white (66.3%), and non-Hispanic (91.2%; Table 1.2). Table 1.2 also shows baseline self-reported use of non-VA care and economic outcomes. Participants in the EMOT group reported a mean of 1.6 (SD 3.8) non-VA outpatient visits at randomization, while participants in the SERV group reported a mean of 1.1 (SD 4.8) non-VA outpatient visits (p=0.427). At randomization, none of the participants in the EMOT group reported a non-VA hospitalization, while 6% of the participants in SERV group reported a non-VA hospitalization in the prior 3 months (p=0.043). However, there was no difference in non-VA hospital use in the 3 months prior to pairing with the dog (2% in both groups; p=0.292).

At randomization, the EMOT group reported a mean impact on daily activities of 5.7 (SD 2.9) as measured on the WPAI, while the SERV group had a mean impact of 5.2 (SD 2.5; p=0.202). The EMOT group reported higher impact of health problems on work productivity (mean 5.7, SD 2.6) than the SERV (mean 3.3, SD 2.2; p=0.001). Neither measure was significantly different at pairing.

Table 1.2 also shows participants' reliance on the VA for health care at baseline randomization. There were no statistically significant differences between the treatment groups in self-reported VA reliance. In both groups, over 90% said that they relied on VA for all their inpatient needs. Reliance on VA for outpatient care was less pronounced than inpatient care, with approximately 10% saying they used mixed sources or mostly non-VA care; nevertheless, over 85% said they used VA for most or all their outpatient care.

Figure 1.3. Summary of Randomization and Pairing



Source: Richerson et al, 2021[1]

Table 1.2. Baseline Characteristics among Participants Paired with a Dog

	Emotional Support Dog Number (Percent)	Service Dog Number (Percent)	p-value*
Gender			0.312
Male	70 (83.3%)	75 (77.3%)	
Female	14 (16.7%)	22 (22.7%)	
Race			0.452
Black	12 (14.3%)	10 (10.3%)	
White	52 (61.9%)	68 (70.1%)	
Multiple Races	15 (17.9%)	16 (16.5%)	
Other	5 (6.0%)	3 (3.0%)	
Ethnicity			0.339
Hispanic	8 (9.5%)	4 (4.1%)	
Not Hispanic	74 (88.1%)	91 (93.8%)	
Unknown	2 (2.4%)	2 (2.1%)	

	Mean (Standard Deviation)	Mean (Standard Deviation)	p-value*
Age	49.2 (13.25)	51.8 (13.87)	0.194
Non-VA Clinic visits			
Randomization	1.6 (3.8)	1.1 (4.8)	0.427
Pairing	1 (2.2)	1 (4.8)	0.96
Non-VA ER Visits			
Randomization	0.1 (0.4)	0.1 (0.3)	0.312
Pairing	0.1 (0.3)	0 (0.2)	0.884
Non-VA Hospitalization (%)			
Randomization	0% (0%)	6% (24%)	0.043
Pairing	2% (15%)	2% (14%)	0.292
Employed (%)			
Randomization	35% (48%)	24% (43%)	0.109
Pairing	34% (48%)	26% (44%)	0.243
If employed, missed work due to health (hours)			
Randomization	6.9 (11.7)	4.2 (9.0)	0.357
Pairing	4.7 (7.3)	3.5 (6.0)	0.5
If employed, missed work for other reasons (hours)			
Randomization	2.8 (7.1)	3.7 (7.7)	0.663
Pairing	5.3 (8.0)	2.0 (3.1)	0.06
If employed, actual hours worked			
Randomization	27.1 (14.1)	26.4 (14.3)	0.851
Pairing	24.3 (12.1)	24.6 (13)	0.914
Health Impact on Productivity (0-10)^			
Randomization	5.7 (2.6)	3.3 (2.2)	0.001
Pairing	4.8 (2.5)	3.8 (2.9)	0.231
Health Impact on Daily Activities (0-10)^			
Randomization	5.7 (2.9)	5.2 (2.5)	0.202
Pairing	5.5 (2.6)	5.1 (2.8)	0.254
Impact of Health on Overall Productivity (0-10)^			
Randomization	5.8 (2.9)	5.0 (2.6)	0.047
Pairing	5.3 (2.6)	4.8 (2.8)	0.251
	Number (Percent)	Number (Percent)	p-value*
How often did you use VA for outpatient care?			0.528
All VA	55 (65.5%)	73 (75.3%)	

Mostly VA	19 (22.6%)	15 (15.5%)	
Mixed	4 (4.8%)	3 (3.1%)	
Mostly Non-VA	6 (7.1%)	6 (6.2%)	
All Non-VA	0 (0.0%)	0 (0.0%)	
Missing	0 (0.0%)	0 (0.0%)	
How often did you use VA for inpatient care?			0.283
All VA	80 (95.2%)	89 (91.8%)	
Mostly VA	2 (2.4%)	1 (1.0)	
Mixed	1 (1.2%)	2 (2.1%)	
Mostly Medicare	1 (1.2%)	0 (0.0%)	
All Medicare	0 (0.0%)	4 (4.1%)	
Missing	0 (0.0%)	1 (1.0%0	

*p-value from random effects regression controlling for month and baseline outcome
^higher number indicates greater impact

1.3.2. Total Healthcare Costs

We found no significant differences between treatment groups in the analysis of total costs (Table 1.3).

Table 1.3. Effect of a Service Dog on Total Healthcare Costs

	Total Costs[a] Marginal Effect (Standard Error)
Service Dog	**$839.29 (869.06)**
Month 6	-$113.59 (709.25)
Month 9	$763.61 (709.25)
Month 12	-$449.73 (709.25)
Month 15	-$499.32 (709.25)
Month 18	-$1,443.39* (709.25)
Male	-$2,251.14* (1,089.36)
VA Station 584	$817.08 (990.52)
VA Station 648	-$419.63 (1,130.34)
Constant	$6,914.66*** (1,292.74)
Observations (n)	1,084

Persons (n)	181

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test); standard errors in parentheses
[a]Total costs estimated using a linear model with random effects
Month 6: 91-180 days post-pairing; Month 9: 181-270 days post-pairing; Month 12: 271-360 days post-pairing; Month 15: 361-450 days post-pairing; Month 18: 451-540 days post-pairing.
All costs adjusted to 2018 dollars.
All regression models were calculated with emotional support group, month 3, and VA Station 508 as reference categories. Positive values indicate higher costs/utilization for the SERV group while negative values indicate lower costs/utilization for the SERV group.

1.3.3. VA Cost and Utilization

Receipt of a SERV did not significantly affect VA costs for any categories of care, as summarized in Table 1.4. Receipt of a SERV also did not significantly affect VA health care utilization, with the exception of outpatient substance abuse treatment (see Table 1.4). Participants in the SERV group experienced significantly greater outpatient substance abuse treatment utilization than participants in the EMOT group. To interpret the negative binomial model, we computed the adjusted mean difference, and SERV participants reported 1.12 (SE 0.56, p=0.045) more outpatient substance use visits in the follow-up period than EMOT participants. The complete regression models are shown in Tables 1.A.1 and 1.B.1.

We examined whether the effect of the SERV intervention varied across the follow-up assessments. Most of the cost endpoints were not significantly different, but we found two significant differences where the treatment effect varied over time. The first was outpatient mental health costs, which were $622.12 significantly higher for the SERV group (SE $305.86, p=0.042) than the EMOT group and this difference decreased over time. This relationship is shown in Figure 1.4. The second was in inpatient psychiatry, but this effect was not consistent across models and was not stable given that it did not occur in the next time period (see Figure 1.5). Table 1.A.4 shows the marginal effect of assignment to the SERV group for total cost and subtotals, where we interact the SERV treatment assignment with the follow-up periods.

For the utilization endpoints, we found no significant effect on most measures of health care utilization, with two exceptions. First, substance abuse treatment utilization for the SERV group was 1.57 visits (SE 0.73, p<0.05) higher than the EMOT group. Second, inpatient length of stay was 2.36 days (SE 1.16, p<0.05) longer for the SERV group. However, these differences were not significant in alternate linear models. Table 1.B.4 shows the marginal effect of assignment to the SERV group for utilization, where we interact the SERV treatment assignment with the follow-up periods.

Table 1.4. Effect of a Service Dog on VA Cost and Utilization: Summary Table[a]

	VA Utilization[b] Beta Coefficient (Standard Error)	VA Costs[c] Marginal Effects (Standard Error)
Total	--	$663.84 (784.37)
Inpatient		
Inpatient Admissions	0.35 (0.53)	$347.96 (493.21)
Inpatient Length of Stay	0.82 (0.49)	--
Inpatient Medical / Surgical	--	-$8.79 (187.36)
Inpatient Mental Health	--	$25.58 (157.04)
Inpatient Other	--	$330.28 (320.04)
Outpatient		
Outpatient visits	0.03 (0.10)	$316.09 (494.99)
Outpatient Medical/Surgical visits	-0.09 (0.13)	-$151.98 (216.63)
Outpatient Pharmacy	-0.08 (0.13)	$41.27 (135.15)
Outpatient Mental Health visits	0.04 (0.13)	$333.66 (258.64)
Outpatient Substance Use visits	1.12* (0.56)	$30.34 (51.67)
Other Outpatient Visits	0.02 (0.13)	$61.50 (139.60)
Observations (n)	1,084	1,084
Persons (n)	181	181

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test)

[a] The full regression results can be found in Tables 1.A.1 and 1.B.1.

[b] VA utilization data produced using a negative binomial model.

[c] VA cost data estimated using a least squares model with person-specific random effect.

All costs adjusted to 2018 dollars.

All regression models were calculated with emotional support group, month 3, and VA Station 508 as reference categories. Positive values indicate higher costs/utilization for the SERV group while negative values indicate lower costs/utilization for the SERV group.

Figure 1.4. Predicted Outpatient Mental Health Costs

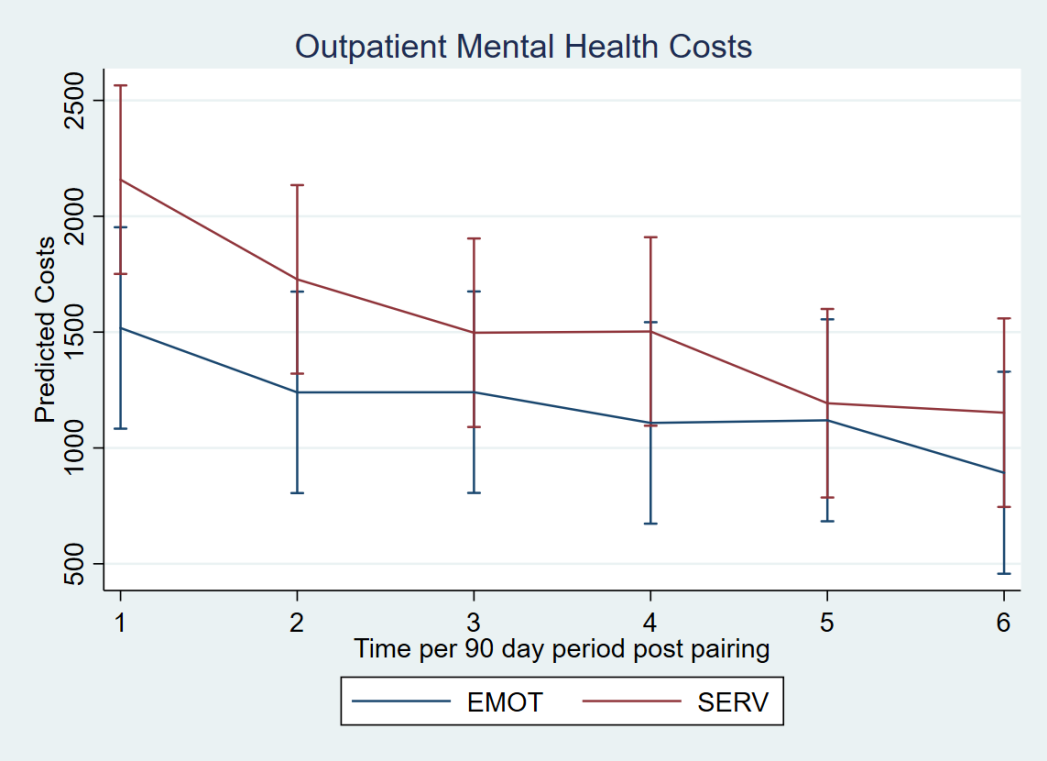
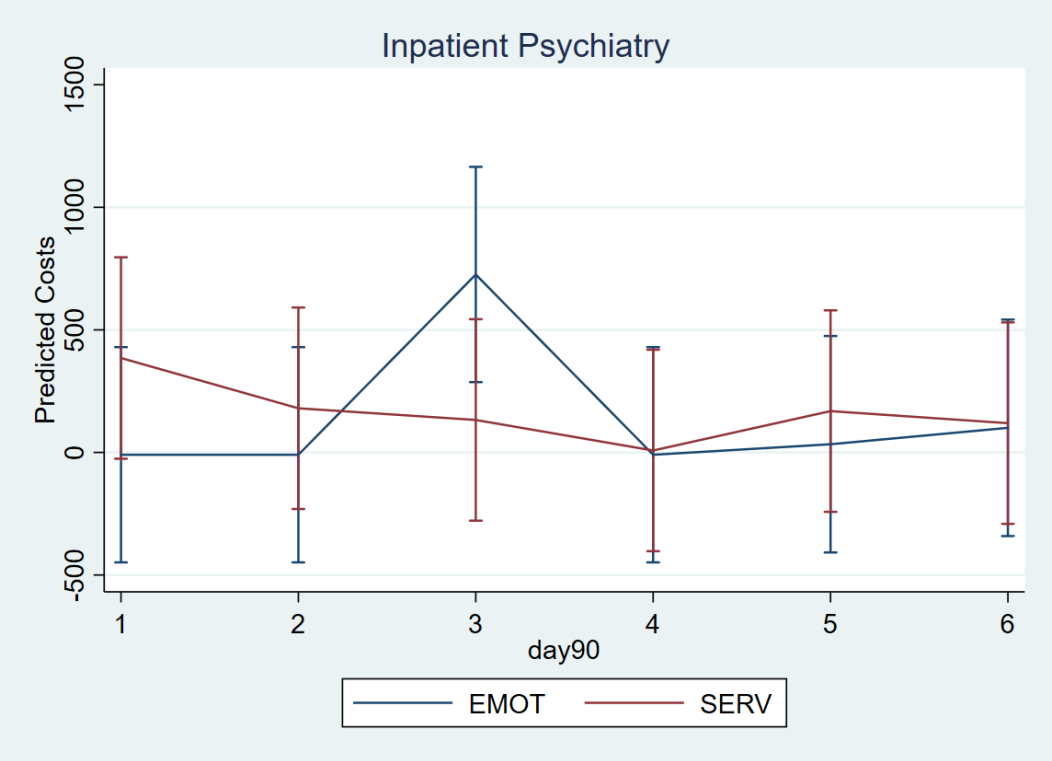


Figure 1.5. Predicted Inpatient Mental Health Costs



1.3.4. Non-VA Utilization

In the follow-up periods, over 90% of the participants said that they received all or most of their inpatient care at VA. Similarly, over 80% of the participants said that they received all or most of their outpatient care at VA over the 18-month follow-up period. In unadjusted analyses of non-VA utilization, there were no significant differences between the EMOT and SERV groups (Table 1.5).

There were no significant differences between the SERV group and the EMOT group for non-VA clinic visits, overnight hospitals visits, or ER visits. Table 1.6 summarizes the results and Table 1.C.1 shows regression models, with complete cases, for non-VA utilization. The reported p-values are from random-effects regressions controlling for baseline values. There were no significant differences between treatment assignment and follow-up time (see Table 1.C.2).

Table 1.5. Unadjusted Use of Non-VA Health Care: Complete Case

	EMOT			SERV		
	n	Mean (Standard Deviation)		n	Mean (Standard Deviation)	p-value
Non-VA Clinic Visits						
Randomization	84	1.6 (3.8)		96	1.1 (4.8)	
Paring	83	1.0 (2.2)		95	1.0 (4.8)	
Month 3	75	0.9 (2.6)		95	0.5 (1.3)	0.430
Month 6	73	1.0 (2.8)		94	0.4 (1.4)	
Month 9	70	1.3 (3.5)		92	0.5 (1.5)	
Month 12	68	0.9 (2.7)		90	0.7 (2.5)	
Month 15	66	1.4 (3.3)		89	0.5 (1.5)	
Month 18	65	0.9 (2.1)		88	0.6 (1.8)	
Non-VA ER Visits						
Randomization	83	0.1 (0.4)		96	0.1 (0.3)	
Paring	83	0.1 (0.3)		95	0.0 (0.2)	
Month 3	75	0.1 (0.3)		95	0.0 (0.2)	0.358
Month 6	72	0.1 (0.3)		94	0.0 (0.2)	
Month 9	70	0.1 (0.6)		92	0.1 (0.3)	
Month 12	68	0.1 (0.4)		90	0.1 (0.3)	
Month 15	66	0.1 (0.3)		89	0.0 (0.2)	
Month 18	65	0.1 (0.3)		88	0.1 (0.3)	
Non-VA Hospitalization (%)						
Randomization	84	0% (0%)		96	6% (24%)	
Paring	84	2% (15%)		97	2% (14%)	

Month 3	76	3% (16%)		94	5% (23%)	0.390
Month 6	73	5% (23%)		94	2% (15%)	
Month 9	70	3% (17%)		91	8% (27%)	
Month 12	67	3% (17%)		90	3% (18%)	
Month 15	66	0% (0%)		88	1% (11%)	
Month 18	64	0% (0%)		88	2% (15%)	

Self-reported utilization was asked about prior 3 months.
* p-value from random effects regression controlling for month and baseline outcome
Sample size (n) reflects the number of participants who provided self-reported non-VA healthcare use information at the time of data collection.

Table 1.6. Effect of Service Dog on Non-VA Utilization and Economic Outcomes: Summary Table[a]

Outcome	Observations (Persons)	Beta Coefficient (95% Confidence Interval)
Non-VA Utilization		
Non-VA Outpatient Visits	961 (170)	-0.19 (-0.68 - 0.29)
Non-VA Hospital Stays	955 (170)	0.38 (-0.49 - 1.26)
Non-VA ER Visits	954 (169)	-0.16 (-0.92 - 0.60)
Economic Outcomes		
Employed	966 (171)	0.64 (-0.79 - 2.07)
Missed Work due to Health	211 (46)	-1.80 (-5.03 - 1.43)
Missed Work Other Reasons	210 (46)	-1.24 (-3.79 - 1.31)
Actual Hours Worked	211 (46)	5.30 (-1.12 - 11.72)
Impact of Health on Work Productivity (0-10)^	182 (40)	-0.06 (-1.51 - 1.38)
Impact of Health on Regular Activities (0-10)^	965 (171)	-0.36 (-0.97 - 0.25)
Impact of Health on Overall Productivity (0-10)^	965 (171)	-0.24 (-0.86 - 0.38)

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test)
^ Higher number indicates more impact
[a] This table summarizes results from the Complete Case analysis.
The full results can be found in Tables 1.C.1 and 1.D.1. The results from the Multiple Imputation analysis can be found in Tables 1.C.3 and 1.D.3.
Sample size reflects the number of participants who provided self-reported non-VA utilization and work productivity and employment information at the time of data collection. Each participant could contribute up to six responses. In the analysis of the impact of health on work productivity, we analyzed only participants who were employed.

1.3.5. Psychiatric Medication Use

Participants who received the service dog intervention experienced 10 percentage point (SE 0.03, p=0.001) greater use of antidepressants (see Table 1.7). The data also indicated a trend towards a decreased use of benzodiazepines and other sedatives/hypnotics, as evidenced by a lower PDC in

benzodiazepines (-7 percentage points) and other sedatives/hypnotics (-8 percentage points); however, these finding were not significant (Table 1.7).

More than 90% of the participants reported using no non-VA medications during the follow-up (see Table 1.8). Melatonin was the most common non-VA or over the counter medication, reported by 5 participants.

Table 1.7. Analysis of VA Pharmacy Proportion Days Covered (PDC), [a] controlling for PDC prior to pairing

	PDC Marginal Effect (Standard Error)					
	Antidepressants	Antipsychotics	Benzodiazepines	Other Sedatives	Antidepressants and Antipsychotics	Benzodiazepines and Other Sedatives
Service Dog	**0.10** (0.03)**	**0.12 (0.11)**	**-0.07 (0.10)**	**-0.08 (0.09)**	**0.09** (0.03)**	**-0.05 (0.06)**
Service dog pre-period	-0.08*** (0.02)	-0.07 (0.08)	-0.05 (0.05)	0.05 (0.07)	-0.08** (0.02)	-0.02 (0.04)
Post-period	-0.03 (0.03)	-0.09 (0.08)	0.10 (0.09)	-0.05 (0.09)	-0.03 (0.03)	0.04 (0.06)
VA Station 584	0.10*** (0.03)	0.12 (0.08)	-0.13 (0.09)	0.21** (0.08)	0.10*** (0.03)	0.02 (0.06)
VA Station 648	0.02 (0.04)	0.06 (0.08)	0.04 (0.12)	0.13 (0.10)	0.03 (0.04)	0.11 (0.08)
Male	0.10** (0.03)	0.01 (0.07)	-0.03 (0.10)	0.06 (0.08)	0.10** (0.03)	0.00 (0.07)
Constant	0.64*** (0.04)	0.70*** (0.09)	0.68*** (0.11)	0.54*** (0.11)	0.64*** (0.04)	0.60*** (0.08)
Observations (n)	542	75	77	74	617	151
Persons (n)	158	38	41	41	159	75

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test)

[a] Participants were only included if they had at least one refill in the drug class

Service Dog is interaction of post-period * group assignment

Table 1.8. Use of Non-VA Medications

	Emotional Support Dog Number (Percent)	Service Dog Number (Percent)
0 Non-VA medications	80 (95.2%)	90 (92.8%)
1 Non-VA medication	2 (2.4%)	6 (6.2%)
2 Non-VA medications	2 (2.4%)	0 (0.0%)
3 Non-VA medications	0 (0.00%)	1 (1.0%)

1.3.6. Work Productivity

Table 1.9 shows the unadjusted economic outcomes for work productivity. At randomization, approximately one third (35%) of the participants in the EMOT group reported working, and this declined to 26% at 18 months. At randomization, approximately a quarter (24%) of the SERV group reported working, and this stayed at 24% at 18 months. The difference between the EMOT group and SERV group was not significant at randomization (p=0.109) or follow-up (p=0.383). The follow-up p-value was from a random-effects regression model.

Table 1.9 also shows number of work hours missed due to health, number of work hours missed due to other health reasons, and total hours worked. These numbers were only reported by those who were working. At randomization, employed participants in the EMOT group reported working 27.5 hours, and this remained relatively constant over 18 months. At randomization, employed participants in the SERV group reported working 27.1 hours, and this increased to 34.6 hours at 18 months. This difference was not significant at randomization (0.851) or follow-up (p=0.106). The reported follow-up p-values are from random-effects regression model.

Reported impact of health on productivity is also shown in Table 1.9. Responses ranged from 0-10, where a high number represented a higher level of impact. The follow-up data indicated that the EMOT group declined in impact on work productivity from a mean of 4.7 (SD 2.6) at 3 months to a mean of 2.7 (SD 2.2) at 18 months. During this same period, the SERV group increased from a mean of 3.4 (SD 2.8) at 3 months to a mean of 3.7 (SD 2.3) at 18 months, however, this difference was not significant.

The follow-up data indicated that the EMOT group declined in impact on daily activities from a mean of 5.4 (SD 2.7) at 3 months to a mean of 4.6 (SD 3.0) at 18 months. During this same period, the SERV group went from a mean of 5.0 (SD 2.5) at 3 months to a mean of 4.3 (SD 2.8) at 18 months. There was no significant difference in the reported impact of health on daily activities (p=0.246). The reported p-values are from random-effects regression controlling for baseline randomization values.

The adjusted effect of the SERV intervention on employment status, missing work due to health, missing work due to other reasons, actual hours worked, and the impact of health on work productivity are summarized in Table 1.6. There were no statistically significant effects for the treatment assignment in the complete case analysis (Table 1.D.1).

Employment and labor market outcomes over time are shown in Table 1.D.2 (complete case). Of the seven outcomes, there was only one significant difference in the complete case analysis. The SERV group reported that their health had a higher impact on work productivity by 18 months (beta = 2.25; 95% CI 0.39, 4.11; $p<0.05$).

Table 1.9. Unadjusted Employment and Labor Market Outcomes: Complete Case

	EMOT			SERV		
	n	Mean (Standard Deviation)		n	Mean (Standard Deviation)	p-value*
Employed (%)						
Randomization	84	35% (48%)		97	24% (43%)	
Pairing	83	34% (48%)		97	26% (44%)	
Month 3	76	36% (48%)		95	23% (42%)	0.383
Month 6	73	32% (47%)		94	24% (43%)	
Month 9	70	29% (46%)		92	24% (43%)	
Month 12	68	28% (45%)		90	23% (43%)	
Month 15	66	27% (45%)		89	28% (45%)	
Month 18	65	26% (44%)		88	24% (43%)	
If employed, missed work due to health (hours)						
Randomization	29	6.9 (11.7)		23	4.2 (9.0)	
Pairing	27	4.7 (7.3)		25	3.5 (6.0)	
Month 3	27	6.3 (10.2)		22	3.9 (9.3)	0.276
Month 6	23	6.2 (9.5)		22	6.3 (8.2)	
Month 9	20	9.4 (14.6)		22	2.4 (4.3)	
Month 12	19	5.2 (9.9)		21	1.5 (3.6)	
Month 15	18	4.3 (7.6)		25	1.6 (3.2)	
Month 18	17	2.4 (4.6)		21	0.8 (3.5)	
If employed, missed work other reasons (hours)						
Randomization	29	2.8 (7.1)		23	3.7 (7.7)	
Pairing	27	5.3 (8.0)		25	2.0 (3.1)	
Month 3	27	4.1 (10.4)		22	2.5 (5.1)	0.340
Month 6	23	4.6 (11.3)		22	1.5 (2.8)	
Month 9	20	1.0 (2.6)		22	2.9 (6.3)	
Month 12	18	2.8 (6.4)		21	1.2 (3.8)	
Month 15	18	4.9 (7.6)		25	0.9 (2.6)	
Month 18	17	2.5 (6.1)		21	1.2 (5.2)	
If employed, actual hours worked						
Randomization	29	29.1 (16.3)		23	27.1 (15.2)	
Pairing	27	25.4 (14.0)		25	26.0 (15.0)	
Month 3	27	29.4 (16.9)		22	29.9 (15.8)	0.106
Month 6	23	27.9 (15.3)		23	33.1 (13.7)	
Month 9	20	26.0 (17.0)		22	36.9 (12.3)	

Month 12	19	26.5 (15.8)		21	35.9 (13.9)	
Month 15	18	28.8 (14.0)		25	34.2 (11.4)	
Month 18	17	27.5 (15.2)		20	34.6 (15.3)	
Impact of Health on Work Productivity (0-10)^						
Randomization	27	5.7 (2.6)		20	3.3 (2.2)	
Pairing	25	4.8 (2.5)		23	3.8 (2.9)	
Month 3	24	4.7 (2.6)		21	3.4 (2.8)	0.932
Month 6	21	4.1 (2.7)		22	3.1 (2.9)	
Month 9	16	3.9 (2.9)		22	2.7 (2.8)	
Month 12	17	3.1 (2.6)		21	3.4 (2.6)	
Month 15	17	3.6 (2.2)		25	3.0 (2.9)	
Month 18	15	2.7 (2.2)		19	3.7 (2.3)	
Impact of Health on Regular Activities (0-10)^						
Randomization	84	5.7 (2.9)		97	5.2 (2.5)	
Pairing	83	5.5 (2.6)		95	5.1 (2.8)	
Month 3	76	5.4 (2.7)		95	5.0 (2.5)	0.246
Month 6	73	5.3 (2.8)		94	4.7 (2.7)	
Month 9	70	5.7 (2.8)		91	4.8 (2.6)	
Month 12	68	5.3 (2.9)		90	4.6 (2.8)	
Month 15	66	4.9 (2.7)		89	4.7 (3.0)	
Month 18	65	4.6 (3.0)		88	4.3 (2.8)	
Impact of Health on Overall Productivity (0-10)^						
Randomization	84	5.8 (2.9)		97	5.0 (2.6)	
Pairing	82	5.3 (2.6)		95	4.8 (2.8)	
Month 3	76	5.3 (2.8)		95	4.9 (2.6)	0.441
Month 6	73	5.3 (2.7)		94	4.6 (2.9)	
Month 9	70	5.6 (2.9)		91	4.4 (2.8)	
Month 12	68	5.1 (2.9)		90	4.6 (2.9)	
Month 15	66	5.0 (2.6)		89	4.6 (3.0)	
Month 18	65	4.6 (3.0)		88	4.4 (2.8)	

* p-value from random effects regression controlling for month and baseline outcome
^higher number indicates greater impact
Sample size (n) reflects the number of participants who provided work productivity and employment information at the time of data collection. In the analysis of the impact of health on work productivity, we analyzed only participants who were employed.

1.3.7. Attrition and Intent to Treat

Table 1.10 presents baseline information for four groups: participants who were randomized to receive a service dog group but never paired (SERV randomized only), participants who were randomized to receive an emotional support dog but never paired (EMOT randomized only), participants who were randomized to and paired with a service dog (SERV paired), and participants who were randomized to and paired with an emotional support dog (EMOT paired).

Table 1.10. Baseline Characteristics by Study Arm and Pairing Status

	EMOT Randomized only	SERV Randomized only	EMOT Paired	SERV Paired	p-value*
Persons (n)	29	17	84	97	
Age: Mean (SD)	50.4 (14.0)	45.5 (13.8)	49.2 (13.3)	51.8 (13.9)	0.294
Male	72%	65%	83%	77%	0.297
Race					0.799
White	72%	59%	62%	70%	
Black	14%	12%	14%	10%	
Other	14%	29%	24%	20%	
Hispanic Ethnicity	10%	0%	10%	4%	0.263
Married or living as married	24%	29%	48%	39%	0.117
Formal Education					0.918
High school or less	21%	18%	21%	15%	
Some college	62%	71%	68%	71%	
Grad school	17%	12%	11%	13%	
Annual Income					0.675
<$30,000	34%	41%	29%	37%	
$30,000-$50,000	55%	35%	51%	44%	
>$50,000	10%	24%	20%	19%	
Physical Disability	38%	29%	35%	32%	0.913
Mental Disability	48%	35%	40%	45%	0.759
Combat exposure	76%	71%	80%	69%	0.419
Hearing impairment	34%	47%	40%	53%	0.209
Visual Impairment	24%	35%	18%	18%	0.33
Mobility Impairment	48%	29%	38%	33%	0.458
Use Alt Therapy for PTSD	41%	41%	38%	37%	0.972
Walk Outside					0.265
Once a week or less	38%	12%	34%	27%	
Once a day	55%	59%	45%	51%	
More than once a day	7%	29%	21%	23%	
Serve Outside US	83%	71%	93%	92%	0.025

Branch of Service (not mutually exclusive)					
Army	55%	53%	52%	54%	0.995
Navy	10%	29%	18%	14%	0.349
Air Force	14%	12%	8%	10%	0.855
Marines	14%	6%	21%	24%	0.294
Coast Guard	3%	6%	0%	2%	0.296
National Guard	7%	12%	12%	10%	0.895
Service period (not mutually exclusive)					
Korean or Vietnam	24%	18%	25%	30%	0.696
1990s (Gulf & Balkans)	17%	24%	37%	24%	0.109
Post 2001: OEF / OIF	48%	65%	39%	39%	0.202
peace	17%	35%	15%	26%	0.167
Other	14%	0%	11%	12%	0.471
Employment					0.948
Work	24%	41%	30%	27%	
Retired	14%	12%	18%	18%	
Other	62%	47%	52%	56%	

*p-value from random effects regression controlling for month and baseline outcome

Table 1.11 presents the effect of a service dog on VA cost and utilization using a multiple imputation model to estimate follow-up costs for those participants who were not paired with a dog. We found no significant differences between the service dog group and emotional support dog group.

Table 1.11. Effect of a Service Dog on VA Costs, Multiple Imputation Model

	VA Costs Marginal Effects (Standard Error)
Total	-338.76 (729.12)
Inpatient	
Inpatient Admissions	-388.52 (456.55)
Inpatient Length of Stay	--
Inpatient Medical / Surgical	86.26 (202.25)
Inpatient Mental Health	-43.07 (157.53)
Inpatient Other	-390.84 (301.41)
Outpatient	
Outpatient visits	3.39 (461.45)
Outpatient Medical/Surgical visits	289.38 (200.94)
Outpatient Pharmacy	-8.77 (119.93)

Outpatient Mental Health visits	-258.95 (237.19)
Outpatient Substance Use visits	-46.80 (47.05)
Other Outpatient Visits	63.10 (131.03)
Observations (n)	1,360
Persons (n)	227

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test)
All costs adjusted to 2018 dollars.
Positive values indicate higher costs for the SERV group while negative values indicate lower costs for the SERV group.

The per protocol analysis using the inverse probability weights also showed no significant differences, and further analyses excluding the 2 participants who did not have shared support did not change the interpretation of the results.

1.3.8. Sensitivity Analyses

Statistical Models

In sensitivity analyses, results largely held consistent with the main analysis, with a few exceptions. In the analysis of VA utilization over time, the linear models indicate that the service dog intervention was associated with higher use of outpatient mental health services (Table 1.B.6), but that difference significantly decreases over time (Tables 1.B.5 and 1.B.6. In Table 1.B.6, this decrease is significant in month 18 only). In the VA cost analysis, the SERV group had significantly higher outpatient substance abuse treatment costs and total inpatient costs in the GEE model (Table 1.A.3 and 1.A.7).

In the exploratory subgroup analysis of outcomes for low versus high PCL-5 at baseline, inpatient length of stay was lower for people with high PCL-5 baseline scores, but there were no other significant differences for any outcomes (results not shown). Finally, in our main analysis, we capped actual hours worked at 50. In the sensitivity analysis, we used actual reported hours worked in the week, which went as high as 99. The results of this analysis were consistent with the main results.

Multiple Imputation for Self-Report Data

The multiple imputation analysis showed similar results to the complete case analysis for non-VA use. The SERV group used fewer outpatient non-VA clinic visits, but this difference was not statistically significant. In the negative binomial model, the adjusted coefficient was -0.42 (95% CI -0.88, 0.03), which reflects a marginal effect of about a half a visit (see Table 1.C.3). With regard to non-VA hospitalization and non-VA emergency room care use, the multiple imputation main results (see Tables 1.C.3 and 1.C.4) were also consistent with the complete case analysis.

There were three significant findings in the work productivity multiple imputation models (Table 1.D.3). The multiple imputation models indicated that participants in the SERV group were more able to maintain their regular daily activities (beta= -0.88, 95% CI -1.57, -0.19; p=0.012) and reported that their health had a lower impact on their productivity (beta= -0.84; 95% CI -1.54, -0.13; p=0.021) than the emotional support dog group. In the results over time, the odds of employment were higher by month 15 for the SERV group than the EMOT group (beta = 2.32; 95% CI 0.06, 4.58; p=0.04) but results were no longer statistically significant by 18 months (p=0.102).

1.4. Discussion

In terms of health care utilization and costs, there were largely no significant differences between Veterans paired with a SERV or an EMOT. There was some evidence that the SERV intervention increased cost and utilization for substance use treatment and mental health services, but these significant effects were not consistent across models or time periods, and could simply be due to chance because of the number of comparisons examined. In addition, the self-report data indicated that the SERV intervention does not improve work productivity outcomes.

Participants in the post-period had higher rates of PDC for antidepressants, indicating that receipt of a dog may lead to improved medication adherence for antidepressants among those who refilled their prescription. Although not significant, participants also experienced lower use of benzodiazepines. One interpretation is that receipt of a dog was associated with using more medications consistent with VA pharmaceutical treatment guidelines for PTSD. That this effect on increased antidepressant PDC was more pronounced in the SERV group, who also demonstrated a trend towards increased utilization of mental health and substance use treatment, suggests that increased treatment engagement may be related to improved adherence to PTSD treatment guidelines for psychotropic medications. However, this is measuring one specific type of adherence (secondary adherenace), and more evidence is needed to better understand these findings.

This study had several limitations worth discussing. First and foremost, is the lack of an intent to treat analysis. This resulted reported here includes only a subset of all persons randomized; of the 227 participants who were randomized, 181 were paired with a dog. We had no authority to examine data for the 46 participants who withdrew, preventing an intent to treat analysis. The attrition between arms was not balanced (15% attrition for SERV and 26% for EMOT) and may have biased study results.

Second, the study has a relatively small sample size (n=181). The small sample size makes it less likely to detect differences that may exist between study arms. A third limitation of the study is a lack of a no dog comparison group. The pre-post analysis indicates that both groups may have improved over the study period. A non-dog comparison would serve to better understand the true

impact of receiving a SERV; however, for reasons stated in the first monograph a no dog group was not possible, primarily because of Veterans' unwillingness to accept this randomization. Forth, this study was limited to a cohort entirely of Veterans; therefore, results may not be generalizable to the civilian population. Additional limitations of the main study are detailed in the first monograph.[1]

One concern impacting generalizability is that the emotional support dogs used in the study may not be representative of "real world" emotional support dogs because of similarities between the study service dogs and study emotional support dogs in terms of breed, health and temperament standardization, and obedience training. VA created standards for the study for emotional support dogs because none existed at the initiation of the study, and to our knowledge, still do not exist. As a matter of ethical responsibility to the Veterans (and their families) who were randomized to the emotional support dog group, VA required emotional support dogs to be obedience trained, well-socialized, and meet the same high health and soundness standards used for the service dogs. In reality, most emotional support dogs in U.S. households are pets with widely varying degrees of training, temperament, and health; therefore, the obedience, socialization, and health standards used for emotional support dogs by VA in the study exceed those of typical emotional support dogs living in U.S. households. The high-quality emotional support dogs used in the study may have resulted in the Veterans randomized to this dog type scoring higher than expected on the outcomes measures than they would have with a more typical emotional support, thus reducing the magnitude of any advantage in the metrics for the service dog group.

Likewise, a similar problem exists related to the study service dogs, which were trained to ADI standards; ADI along with IGDF sets the standards for their member organizations. The fact remains that no specific training or temperament requirements for service dogs are universally accepted in the U.S. As specified in the provisions of the U.S. Americans with Disabilities Act, the handler is afforded the right to designate a dog as a "service dog," which includes dogs self-trained by their handlers who are not dog trainers, dogs trained by organizations that are not accredited by ADI/IGDF, and pets that not trained at all. Therefore, the study findings are best viewed as a comparison of high-quality skill task-trained service dogs to equally high-quality obedience trained emotional support dogs.

In conclusion, receiving a SERV may improve antidepressant and evidenced-based medication adherence compared to an EMOT. There was no evidence, however, that receiving a SERV would reduce health care utilization or health care costs compared to an EMOT. The employment and work productivity outcomes also showed no improvements, although the estimates were often imprecise, likely due to the sample size. The mixed findings could be due to several possibilities including the limited duration of study follow-up, and the use an active comparator group, which introduces challenges in interpreting null effects.[44] Given these mixed findings, a separate cost-effectiveness analysis was conducted and is reported in the next chapter.

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Chapter 2

Service Dogs for Veterans with Post-Traumatic Stress Disorder: Cost-Effectiveness and Suggested Pricing Benchmarks

2. Abstract

Post-traumatic stress disorder (PTSD) is a mental health disorder that disproportionally impacts Veterans and is associated with long-lasting clinical, patient-centered, and economic consequences. The US Department of Veterans Affairs (VA) conducted the first randomized clinical trial to evaluate whether service dogs (trained in mental health specific tasks) could improve PTSD clinical outcomes and/or provide any economic savings to the health care system. Previous trial analyses examined mental health and patient-centered outcomes and compared the economic outcomes of Veterans randomized to pairing with service dogs (SERV) versus emotional support dogs (EMOT, trained in obedience only).

The objective of this chapter is to evaluate the cost-effectiveness of SERV for Veterans with PTSD at the prices paid for this service within the clinical trial. The primary analysis compared the SERV intervention to the EMOT intervention. We used a decision-analytic model to estimate incremental costs and outcomes over a lifetime time horizon. Relative clinical effectiveness was based on clinical trial between group differences seen in the PTSD Civilian Checklist 5 (PCL-5). We assumed a perspective of a comprehensive health system payer responsible for paying all costs related to the procurement and insurance for these dogs and conducted sensitivity analyses to characterize uncertainty. Given that the clinical trial found no statistical differences in employment and productivity between the two interventions, we conducted a societal perspective threshold analysis. . In a different threshold analysis, we assumed the payer perspective of the VA which does not pay for procurement or pairing of dogs but does pay for the insurance costs of the eligible SERVs. In this "VA payer" perspective threshold analysis, we solved for the symptom improvements needed for the SERV intervention to be considered cost-effective if one were to evaluate a study that compares SERV to usual care (no dog).

Comprehensive Health System Payer Primary Findings (including procurement and insurance costs; versus the EMOT intervention): The SERV intervention has small increased health benefits, 0.039 quality-adjusted life years (QALYs) gained (95% interval: -0.0006 to 0.1074) and increased costs compared to the EMOT intervention, $9,800 (95% interval: -$4,700 to $24,400), resulting in an incremental cost-effectiveness ratio of $249,000 per QALY gained (95% intervals not reported due to different meanings of negative values). SERV bundled pricing over seven years, inclusive of insurance costs, would require a reduction of 14% -- from $42,478 to $36,498 -- to meet a commonly cited cost-effectiveness threshold of $100,000 per QALY gained. The impact of uncertainty in clinical and economic inputs can be assessed through probabilistic cost-effectiveness findings (e.g., at current pricing, there is a 20% probability of achieving $100,000 per QALY gained).

The societal perspective threshold analysis suggests favorable cost-effectiveness findings for SERV if cost savings can be demonstrated by increases in Veteran weekly work hours (SERV vs. EMOT).

VA Payer Threshold Scenario Findings (SERV insurance costs only; health gains needed to achieve cost effectiveness versus no dog): Assuming no evidence of cost savings, the PCL-5 symptom improvement versus usual care without a dog would need to be at least -15.8 units for the SERV intervention to be cost-effective at $100,000 per QALY gained. Unadjusted pre-post trial analyses that do not permit causal interpretations of the findings yielded -15.4 units on the PCL-5 total score.

Limitations of our cost-effectiveness analysis include the uncertainty in the PCL-5 and corresponding relationship to quality of life utilities used in the model; the lack of longer-term data on effects of the SERV intervention including potential differences in suicide rates; and the inability to use the trial evidence to directly compare the SERV intervention to usual care without a dog.

In conclusion, the comprehensive health system payer perspective findings suggest that a 14% reduction in SERV bundled pricing (i.e., one-time SERV acquisition and pairing costs plus annual veterinary insurance) would be needed to achieve a commonly cited cost-effectiveness threshold of $100,000 per QALY. The VA payer threshold analysis comparing SERV to no dog suggests health gain targets for future studies to achieve favorable cost-effectiveness findings. These findings are subject to uncertainty and, ultimately, cost-effectiveness is but one element that decision-makers should consider in a broader judgment of value.

2.1. Background

2.1.1. Overview

As described in the VA's first monograph on the mental health outcomes of service dogs (SERV) compared to emotional support dogs (EMOT) for Veterans with post-traumatic stress disorder (PTSD),[1] PTSD is a mental health disorder that typically manifests after an individual experiences one or more significant traumatic events, and is a major source of physical and mental health disability for military Veterans. Symptoms include recurrent and intrusive memories of the traumatic event, avoidance and extreme sensitivity to experiences similar to the triggering event, and feelings of guilt or blame.[2] Veterans with PTSD are at increased risk for overall mortality and also have substantially higher rates of completed suicide (50% greater) than the general, non-Veteran population.[3-6] PTSD has immense impacts on patients' quality of life and ability to function, and is frequently accompanied by comorbid mental health disorders like personality, mood, anxiety, and substance use disorders.[7] The prevalence of PTSD is higher among United States (US) military Veterans (estimates range from 12-30% lifetime prevalence) than the general US population (approximately 8%), and it is twice as common in women than men (10.4% vs. 5%).[8-14] Veterans who have deployed are more likely to develop PTSD.[15] Nearly 400,000 Veterans were diagnosed with PTSD between fiscal years 2002 and 2015.[16]

PTSD also affects caregivers and family members, who spend substantial time caring for and worrying about their loved one. They often take on a larger role in household tasks that the individual with PTSD is unable to perform. Veterans with PTSD are more likely to have marital problems, including difficulty with intimacy. Family violence (verbal or physical) is also more common.[17]

The economic effects of PTSD for the health system are substantial, as described in the economic trial analysis (Chapter 1),[18] with the VA spending over $3 billion on its treatment in 2012.[19] On average, Veterans with PTSD incur twice the annual health care costs each year as those without.[20] Veterans with PTSD are 19% less likely to be employed, and individuals with depression, a common comorbidity, are often less productive.[21]

Traditional therapies for PTSD include pharmacologic interventions (i.e., anti-depressants and anti-adrenergic agents) and psychotherapy (i.e., prolonged-exposure therapy and cognitive processing therapy). The authors of the first monograph note that although these evidence-based therapies lead to improvements for many Veterans with PTSD, there is still a substantial unmet need for adjunctive therapies because for many patients, these treatments do not provide adequate improvement in symptoms.[1] One such intervention described in the first monograph is the pairing of patients with dogs that can provide emotional support (pet dogs) versus dogs trained to perform specific tasks to assist their owners in easing disability.

Dogs have been used as adjunctive therapies for psychiatric patients since at least 1919. They have served as guide dogs for Veterans who have lost their sight or hearing and as support for those who have mobility disorders.[22] The health benefits of dog companionship are well-documented. When compared with individuals who do not own a dog, dog owners have a slower resting heart rate,[23,24] lower blood pressure,[23-27] lower cholesterol, better triglyceride levels,[26,27] longer post-myocardial infarction (MI) survival,[25,26] and better pain management.[28] There is also evidence to demonstrate that dogs reduce levels of stress and anxiety,[29] improve mood,[25,30] reduce depression,[29,31] fear, anxiety,[29,30,32] and aggression, among other symptoms of mood disorders.

There are two types of dogs that may reduce symptoms in patients with PTSD: SERV and EMOT. SERV are working dogs, not pets, described under the Americans with Disabilities Act (ADA) as "a dog that is individually trained to do work or perform tasks for a person with a disability."[33] Under the ADA, SERV may accompany their handler in public spaces, workplaces, on public transit and airplanes, and are permitted in all forms of housing provided the animal is well behaved.[33] The ADA specifies a few behavioral requirements for service dogs but does not include health and training requirements. Assistance Dogs International (ADI), a coalition of non-profit organizations that train and place SERVs, maintains the most widely recognized international training and health standards for service dogs and notes that there are a broad range of potential tasks suited to the individual needs of handlers, "including but not limited to: pulling a wheelchair, bracing, retrieving, alerting to a medical crisis, and providing assistance in a medical crisis."[34] For individuals with mental health disorders, SERV can be trained to remind their owner to take medicine, search rooms to determine if someone else is present, interrupt self-harm or nightmares, or remove their owner from dangerous situations.[1]

SERV may be bred or purchased from breeders by training organizations, as was exclusively the case in the VA randomized clinical trial, or they may be rescue animals that are trained later in their lives.[1] SERV may be any breed that is suitable for their tasks; larger breeds are considered more appropriate for physical tasks like pulling a wheelchair, while both small or large breeds can perform hearing assistance tasks (e.g., alerting their handler to noises like alarms, doorbells, and ringing phones).[35] SERV candidates should be calm in all settings, attentive, eager to please, trainable, well-socialized to a variety of environments and situations, and reliably perform their trained tasks. Most dogs are not suitable for the role of a SERV, with professional training organizations reporting washout rates of 50 to 70% or higher.[35] Professional organizations pair handlers with SERV that are appropriate for their disability status, work and home environment, personality, activity level, and family. Such organizations offer one- to two-week courses to train handlers to use their SERV and to ensure dog and handler are bonding as expected.[36,37]

EMOT, in contrast, must be prescribed by a licensed mental health professional as a treatment for a mental illness, but are otherwise similar to pet dogs.[38] ADI defines an EMOT as a "companion animal that provides emotional or therapeutic support to an individual with a mental health condition or emotional disorder simply by being present."[34] Emotional support dogs are essentially

pets; they may be purebred or mixed-bred dogs, which may or may not be obedience trained. There are no training standards or requirements for EMOT, though they should be well behaved.[39] EMOT have fewer legal protections than SERV and typically cannot enter the workplace and other public spaces. Individuals with disabilities may live in housing without being charged extra rent because of their EMOT.[40] Until recently, handlers could bring their EMOT on flights without paying an additional fee. On December 2, 2020, the US Department of Transportation (DOT) issued a new rule removing this protection due to increased reports of dog aggression and misbehavior in cabins, which were generally attributed to poorly-behaved pets being passed off as EMOT to avoid airline surcharges.[41] Airlines may now require handlers to complete DOT forms attesting to their SERV's health, behavior, and training, as well as other requirements related to sanitation.[43] The new DOT policy requires airlines to treat physical and psychiatric SERV the same (i.e., any SERV that can fit in their handler's leg space may fly in the cabin for free).

Given these differences, questions remain regarding the magnitude of health or broader benefits provided by SERV and EMOT for Veterans with PTSD, and whether SERV, which are more expensive, provide greater benefits.

The VA currently provides a comprehensive veterinary insurance policy that covers wellness, illness/injury, prescription medications, and routine veterinary health checkups with no out-of-pocket expenses to Veterans for SERV that perform hearing, guide, and mobility tasks. Mental health SERVs are not covered except for "mental health mobility service dogs" that assist Veterans who have a mobility disorder that is linked to a mental health disorder (agoraphobia), and for which they have been identified as the optimal treatment.[44] With the exception of the study described in the first monograph, the VA does not purchase SERV for eligible Veterans; rather, Veterans are referred to an ADI or International Guide Dog Federation-accredited agency and the cost of the dog is typically covered through donations.[45] Veterans are responsible for other costs associated with their SERV, including nonprescription food, grooming, nail trimmings, and boarding or other pet-sitting services.

In the 2010 National Defense Authorization Act, Congress required the VA to conduct a study of the mental health benefits, including quality-of-life improvements, and economic impacts of SERV for the treatment of physical and mental health injuries or disabilities, including PTSD.[46] The VA therefore began an initial (Phase I) three-year study in 2011 which compared outcomes in Veterans with PTSD who received a SERV plus usual care with those who received usual care alone. An unexpected challenge was the inability to recruit Veterans to the usual care-only group; only one Veteran was willing to be placed in the usual care arm. The study was later suspended due to several adverse events related to the dogs, including bites experienced by children, dogs suffering from hip dysplasia, and the death of a SERV due to an undisclosed coagulation disorder.[1] The VA applied lessons from the Phase I study effort in the subsequent randomized clinical trial (Phase II) that compared outcomes in Veterans paired with a highly-trained SERV versus those paired with an obedience trained-only EMOT.[1,18] The first monograph provides extensive background, trial design

information and reports the results of the Phase I and II studies.[1] In Chapter 1, economic outcomes of both groups were evaluated.[18] Chapter 1 describes the economic effects of PTSD,[1,18] and the effect of the SERV and EMOT interventions on Veterans with PTSD. The VA engaged our team at the Institute for Clinical and Economic Review (ICER) to produce an assessment that would use the results of the trial to perform a cost-effectiveness analysis.

2.1.2. VA Trial Interventions

In the VA trial, both SERV and EMOT were required to be one of the following breeds: Labrador Retriever, Golden Retriever, Labrador/Golden Retriever hybrid, or German Shepherd Dog. SERV and EMOT were screened to ensure they were free of health issues (e.g., hip dysplasia) that would prevent them from performing their tasks and/or shorten their working life. In addition, SERV and EMOT were required to pass the American Kennel Club (AKC) Canine Good Citizen Certification, which is used to assess good behavior and obedience.[1]

EMOT were also required to pass AKC Community Canine Test, which tests the dog's obedience in community settings. Veterans in the EMOT arm participated in a one- to two-day training course on how to handle their dog.[1]

SERV were required to pass the ADI Public Access Test.[41,42] Veterans in the SERV group participated in one week training courses that covered obedience commands, dog care, public access rights, and how to command their SERV to perform the following five tasks:[1]

- ***Block***: The dog stands in front of its handler to provide a non-aggressive physical buffer between the Veteran and others.
- ***Behind***: The dog stands behind the handler to provide a physical buffer, as with the "block" command.
- ***Lights***: The dog locates and turns on a wall-mounted light switch.
- ***Sweep***: The dog searches a room or other space for another person and seeks a treat if someone is found.
- ***Bring***: The dog retrieves an object for the handler.

Table 2.1.1. Interventions of Interest in the VA Trials

Intervention	Behaviors and/or Tasks	Access Rights	Passed Examinations
Emotional support dogs (EMOT)	Provide emotional support	Housing and other areas where pets are allowed	AKC Canine Good Citizen AKC Community Canine
Service dogs (SERV)	Trained to perform specific tasks/jobs. Mental health SERV evaluated in the VA trial were trained to perform block, lights, sweep, bring, and behind commands.	Housing, workplaces, public spaces, airplanes, other areas where allowed by the ADA[33]	AKC Canine Good Citizen Ability to perform the 5 tasks ADI Public Access Test

ADA: Americans with Disabilities Act, ADI: Assistance Dogs International, AKC: American Kennel Club, VA: United States Department of Veterans Affairs

2.1.3. VA Trial Outcomes

VA Trial Clinical Outcomes and Findings

Consistent with the VA trial, the mental health outcomes (and main between group findings) were considered for inclusion into the cost-effectiveness analyses, with an emphasis placed on outcomes with observed group differences as outlined in the VA trial findings. Table 2.1.2 provides a description of each metric, and the between-group finding from the VA trial.

Table 2.1.2. Trial-Informed Clinical Outcomes

Clinical Metric	Description of Metric	Finding from VA Trial
PTSD Civilian Checklist 5 (PCL-5)	The PCL-5 was used to assess change in PTSD symptoms. It is a 20-item self-report measure that assesses the 20 DSM-5 symptoms of PTSD. Each symptom is scored on a scale of 0 (not at all) through 4 (extreme). A total symptom severity score is calculated by summing the scores for each of the 20 items. Scores can range from 0 to 80, with higher scores representing greater symptom severity. The recommended minimum change in score for determining whether an individual has responded to treatment is 5 points, while the recommended minimum change to determine if improvement is clinically meaningful is 10 points.[47]	Adjusted analysis suggested a 3.7-point improvement (p-value 0.0360, standard error 1.75) (lower score=less symptoms of PTSD) in the PCL-5 total score for SERVs versus EMOTs over the 18-month follow-up within the trial. The mean score in the EMOT group at 18 months was 35.25 and was 31.66 in the SERV group.
World Health Organization Disability Assessment Scale II (WHO-DAS 2.0)	Used to assess function and activity limitations (e.g., disability). It is a 36-item questionnaire that assesses functioning in six domains during the prior 30 days.	No between group differences were observed.

Clinical Metric	Description of Metric	Finding from VA Trial
Veterans Rand 12 Item Health Survey (VR-12)	Used to assess health-related quality of life. It is a 12-item self-administered health survey that assesses health-related quality of life.[48] The VR-12 is a modification of the VR-36, a generic health status measure that has been shown to be valid and reliable in a wide variety of healthcare settings.[49,50]	No between group differences were observed.
Pittsburgh Sleep Quality Index (PSQI)	Used to assess sleep quality, sleep latency, sleep duration, and other sleep-related factors	No between group differences were observed.
Columbia-Suicide Severity Rating Scale (C-SSRS)	Used to assess suicidal ideation.[51] It asks questions about suicidal ideation, intensity of ideation, and suicidal behavior.	No between group differences were observed.
Patient Health Questionnaire (PHQ-9)	The PHQ-9 was used to assess severity of depression[52]	No between group differences were observed.
Dimensions of Anger Reactions (DAR)	A seven-item scale that assesses anger disposition directed to others.[53]	No between group differences were observed.

DSM-5: Diagnostic and Statistical Manual of Mental Disorders, EMOT: Emotional support dog, PTSD: post-traumatic stress disorder, SERV: Service dog

VA Trial Economic Outcomes and Findings

Table 2.1.3 provides a description of the healthcare resource use outcomes and the between-group findings from the VA trial.

Table 2.1.3. Trial-Informed Economic Outcomes

Healthcare Resource Use	Description of Resource Use	Finding from VA Trial
VA Healthcare Utilization and Cost	VA Healthcare utilization included VA administrative data to identify VA utilization and cost information for the study participants. The VA Trial identified inpatient, outpatient, and pharmacy utilization and costs using the Managerial Cost Accounting inpatient treating specialty and outpatient files. Medication information was extracted from the Managerial Cost Accounting Pharmacy file.	No between group differences were observed for VA costs for any categories of care. Although post-baseline trends were observed for higher proportion of days covered of antidepressants for the group randomized to SERVs, there were no statistically significant differences. Significant differences were observed for antidepressants and antipsychotics (higher proportion of days covered for the SERVs group) once pre-baseline proportion of days covered were included within the analyses.
Non-VA Healthcare Utilization and Cost	Participants were surveyed about non-VA Inpatient Care and non-VA Outpatient Care Survey.[54] The survey documents outpatient, inpatient and Emergency Department visits to non-VA providers.	No between group differences were observed for non-VA health care utilization for outpatient, hospitalization, or emergency department care. Participants received 90% of their inpatient and 80% of their outpatient care in the VA.
Medication Log	A log of all non-VA medications and sleep aids used by participants was maintained throughout the study.	No between group differences were observed for non-VA medication use.
Work Productivity and Activity Impairment Questionnaire: General Health Problem V2.0 (WPAI:GHP)	A 6-item survey that assesses employment and productivity. It documents work missed due to health and other problems, as well as the effect of the health problems on productivity while at work. Participants provide information about the number of hours worked and missed due to health problems, as well as the extent to which health problems impacted their ability to work and to conduct other daily activities. WPAI outcomes were expressed as impairment percentages, with higher numbers indicating greater impairment and less productivity.	There were no statistically significant effects of the intervention on employment status, missing work due to health, missing work due to other reasons, actual hours worked, and the impact of health on work productivity in the complete case analysis. The multiple imputation models suggested a lower score on how health affects regular activities and a lower impact of health on overall productivity for the SERV group.

HERC: Health Economics Resource Center, VA: United States Department of Veterans Affairs, SERV: Service Dog

2.2. Stakeholder Viewpoints

In conversations and written public comments, Veteran Service Organizations (VSOs) highlighted the substantial need for additional effective PTSD treatments and highlighted Veteran's positive perceptions of the benefits of SERV. Many news articles provide supporting anecdotes, highlighting Veterans who said that their SERV reduced anxiety and depression, helped them with daily activities, and, in some cases, kept them from attempting suicide.[55-57] Veterans paired with SERV must also feed, exercise, and maintain their dog's ability to perform their tasks; one Veteran quoted in the *New York Times* said, "A dog can give you a sense of purpose that a pill will just not ever do."[57] Stakeholders almost universally expressed hope that these benefits would help Veterans improve their health, quality of life, return to work or community engagement, and participate in social activities.

One VSO noted that paralyzed or disabled Veterans, including those with conditions like multiple sclerosis or amyotrophic lateral sclerosis (Lou Gehrig's disease), may receive even greater benefits. These Veterans may be paired with SERV trained to perform mobility tasks as well as those related to PTSD. SERV provide mobility-impaired Veterans, as well as Veterans without mobility issues, with a sense of independence that brings important mental health benefits as they can rely on their dog to perform tasks that would otherwise require human assistance. Paralyzed and mobility-impaired Veterans also face stigma in public settings due the visible nature of their impairments and the presence of a SERV or EMOT may ease social interactions. One VSO reported that a Veteran said, "It helps me to have conversations that I wouldn't have otherwise."

Several mental health experts noted uncertainty around whether SERV or EMOT would improve or reduce the effectiveness of exposure therapy, in which individuals with PTSD are exposed to a trigger in a safe environment so that they can work through their anxiety with the assistance of a mental health professional. There is some concern that the presence of a dog might attenuate the benefit of exposure therapy because of their soothing presence. On the other hand, the same experts noted that exposure therapy can be very stressful for some Veterans, so a SERV or EMOT may help some Veterans try a therapy that they would not otherwise be able to tolerate.

Several mental health professionals and accrediting organizations highlighted the risk of fraud where a handler may attempt to pass an EMOT off as a SERV to enter public spaces where EMOT are prohibited. Indeed, the investigators in the VA trial were aware and concerned that individuals randomized to the EMOT arm would attempt to pass their dogs off as SERV; the open-ended survey collected at study exit may help address this concern.[1] One representative from a SERV trainer coalition noted that because EMOT are not required to meet training standards, they may be more likely to behave poorly or aggressively in unfamiliar settings (e.g., airplanes or workplaces) in comparison to highly-trained SERV. As noted earlier, the DOT recently revoked the right of EMOT to travel with their owners on flights for free.

Training sites and an accrediting organization also noted that geography may pose barriers to some Veterans. Typically, Veterans are paired with a SERV appropriate for the Veteran's personality, living environment, and levels of physical activity. Veterans learn how to handle their dog, what legal rights they have, and start to bond with their SERV during a one- to two-week pairing class that is conducted at the SERV provider's place of business.[37] A lack of access to or reliable transportation to a SERV provider location may prevent some individuals from attending a SERV pairing class, obtaining recertification for public access (if required by the provider organization), or receiving additional training. This concern may decrease if more SERV provider organizations are established to meet rising demand.

2.3. Potential Other Benefits and Contextual Considerations

Our reviews seek to provide information on potential other benefits offered by the intervention to the individual Veteran, caregivers, the delivery system, other patients, or the public that was not available in the evidence base nor could be adequately estimated within the cost-effectiveness model. These elements are listed in the table below, with related information gathered from VSOs and other stakeholders.

Table 2.3.1. Categories of Potential Other Benefit and Contextual Considerations

Potential Other Benefit or Contextual Consideration	Relevant Information
Whether the intervention represents a similar or novel mechanism of action compared to that of other active treatments.	SERV and EMOT represent a new approach to the treatment of PTSD, which is traditionally managed through behavioral health interventions and pharmaceutical treatments.
Whether the delivery mechanism or relative complexity of the intervention under review is likely to produce very different real-world outcomes relative to an active comparator than estimated from clinical trials.	SERV and EMOT require substantial support from their owners in the form of feeding, exercise, and, for SERV, the tasks must be regularly used to ensure they continue to perform their trained tasks. Veterans with comorbid mental health illness such as psychosis, substance use disorder, and other moderate to severe psychological illnesses may pose a risk to themselves or the dog, or these comorbidities may prevent them from properly caring for the dog. Different SERV provider organizations sites may produce dogs of variable quality; therefore, adherence to training standards to ensure that sub-par dogs are not paired with Veterans is paramount. Expert input indicated that the SERV and EMOT in the VA trial may both be of higher quality than those that are readily available in real-world settings.
Whether the intervention differentially benefits a historically disadvantaged or underserved community.	Many argue that America owes Veterans a special debt in reflection of their service and sacrifice for the nation, especially those who sustained physical or mental injuries in the line of duty. Some VSOs noted that mental health has been historically undertreated and not covered by insurance to the same degree as physical ailments. The VA provides a veterinary insurance benefit to Veterans with SERV for visual, hearing, or substantial mobility impairment, so expanding coverage to Veterans with PTSD would be a step toward parity.
Whether there is a notably large or small health loss without this treatment as measured by absolute QALY shortfall.	The absolute QALY shortfall for individuals with PTSD versus those without is 9.02. For comparison, the absolute QALY shortfall for treatment-resistant major depression is 8.7, for cystic fibrosis is 4.23, and for moderate-to-severe ulcerative colitis is 6.2. See Appendix Table 2.B1 for additional comparisons against absolute QALY shortfall in other diseases.

Potential Other Benefit or Contextual Consideration	Relevant Information
Whether there is a notably large or small health loss without this treatment as measured by proportional QALY shortfall.	The proportional QALY shortfall for individuals with PTSD versus those without is 0.36 (36%). For comparison, the proportional QALY shortfall for treatment-resistant major depression is 0.30 (30%), cystic fibrosis is 0.62 (62%), and moderate-to-severe ulcerative colitis is 0.19 (19%). See Appendix Table 2.B1 for additional comparisons against proportional QALY shortfall in other diseases.
Whether the intervention will significantly reduce the negative impact of the condition on family and caregivers vs. the comparator.	VSOs noted that care partners can spend substantial time assisting their loved ones with daily activities such as traveling and worrying about their health. SERV may partially alleviate these impacts. Caregivers of Veterans with PTSD and a mobility disorder may receive additional benefits, as Veterans could be paired with a SERV trained to perform mobility assistance tasks on top of those related to PTSD symptoms.
Whether the intervention will have a significant impact on improving return to work and/or overall productivity vs. the comparator.	PTSD causes substantial negative impacts on employment and productivity. Improvements in PTSD symptoms from either SERV or EMOT are likely to result in employment and productivity improvements for Veterans. Similarly, retired Veterans may be more able to engage in their communities with the support of SERV or EMOT. The VA trial found no statistically significant differences between employment and productivity outcomes between SERV and EMOT. However, SERV may accompany their handlers to workplaces under ADA protections, while EMOT may not, which represents an important real-world advantage for SERV.

ADA: Americans with Disabilities Act, EMOT: Emotional support dog, PTSD: post-traumatic stress disorder, QALY: quality-adjusted life year, SERV: Service dog, VA: United States Department of Veterans Affairs, VSO: Veteran Service Organization

2.4. Long-Term Cost-Effectiveness

2.4.1. Introduction

Health care systems face many policy questions related to the adoption of an intervention, including whether the intervention achieves a positive benefit-harm profile within its indicated population. Regulatory bodies such as the US Food and Drug Administration (FDA) impose evidence-based requirements on drug interventions such that random chance is not a likely reason for concluding that a drug's benefits outweigh its harms. Such evidence-based requirements generally rely on frequentist rules of inference and corresponding hypothesis testing (e.g., p-values < 0.05 and 95% confidence intervals). These benefit-harm assessments are typically met by way of randomized controlled trials. Given the high costs and evidence standards required to reverse a regulatory approval of a drug, the FDA supports this hypothesis testing approach that lends itself to clinical conclusions of the superiority of an intervention versus its comparator.

A natural extension of a conclusion that the health benefits outweigh the intervention's harms is to consider whether the intervention should be included within an insurance benefit based on existing evidence. To address adoption and payment questions, health economists may take a Bayesian decision-theoretic approach.[58-60] This approach suggests that adoption decisions cannot be deferred given that deferral is a choice to continue supporting the current standard of care and does not address the opportunity cost of deferral. The objective of most health systems is to maximize health subject to budget and other constraints. Thus, if an intervention's benefits outweigh its harms, the decision to adopt and pay for an intervention may be addressed by estimating the mean net health benefit irrespective of frequentist or Bayesian confidence/credible intervals. To estimate the mean net health benefit from a cost-effectiveness study, one requires the following from the intervention and comparator: average lifetime discounted costs, average lifetime discounted effectiveness measure, and a threshold that converts the costs into a measure of health foregone (e.g., dividing the lifetime costs by $100,000 per quality-adjusted life year [QALY]). If the intervention's mean net health benefit is greater than that of its comparator, then the Bayesian decision-theoretic approach supports considering the adoption of the intervention. Uncertainty in the mean net health benefit and corresponding decision uncertainty remain useful for prioritizing future research.

2.4.2. Cost-Effectiveness Methods Overview

Our objective was to estimate the cost-effectiveness of SERV for Veterans with PTSD. We used clinical and economic analyses from the Department of Veterans Affairs randomized clinical trial, entitled "Can Service Dogs Improve Activity and Quality of Life in Veterans With PTSD?" [1,18,61] as well as other supporting evidence sources. Cost-effectiveness was estimated using incremental cost-effectiveness ratios. Consistent with the interventions studied in the trial, the primary analysis

compared SERV to EMOT. The primary analysis assumed a comprehensive health system payer perspective that focuses on all relevant direct medical care costs. This perspective includes the initial pairing and procurement-related costs and the insurance-related maintenance costs of the dog as well as annual direct medical care costs. We used a decision-analytic model to convert and forecast trial findings (e.g., between group differences in PTSD Civilian Checklist 5 (PCL-5) and corresponding relationship to quality-of-life utilities) to estimate incremental costs and outcomes (e.g., QALY) over a lifetime time horizon. We included supporting sensitivity and scenario analyses (e.g., societal perspective and a current VA payer perspective with a threshold analysis to support future research).

Consistent with ICER's reference case and Value Assessment Framework[62] as well as other health technology assessment best practices,[63] we conducted a cost-effectiveness analysis that forecasts the trial's outcomes beyond the duration of the trial of 18 months to the average dog Veteran pairing duration in order to comprehensively capture the potential costs and benefits that accrue after trial completion over a Veteran's lifetime. Measures of effectiveness included life years gained, QALYs gained, equal value of life years gained (evLYG), and other disease-specific measures. evLYGs are a measure included within ICER's Value Assessment Framework that assign equal utility scores during an intervention's life extensions, no matter the health status of individuals, thus serving as a measure with some properties consistent with QALYs gained and other properties consistent with life years gained. Life years gained and evLYGs were measured but were not anticipated drivers of the base-case cost-effectiveness findings given no observed differences in mortality across the two trial interventions. Costs and outcomes were discounted at 3% per year following current recommended best practice.[63]

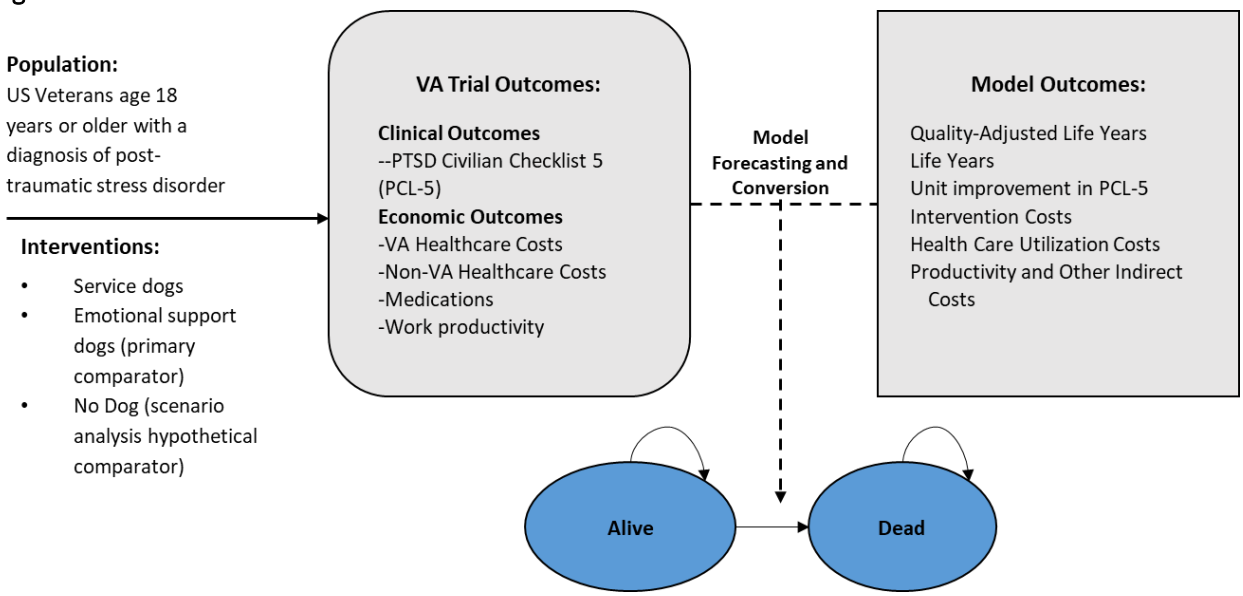
2.4.3. Model Structure

The primary analysis focused on the observed group mean differences and corresponding uncertainty from outcomes in the VA trial. [1,18,61] We converted and forecasted these differences into lifetime costs and outcomes. The schematic for this assessment is depicted in Figure 2.4.1 and shows main features of the analysis. The trial-informed costs and clinical outcomes were forecasted using a two-state Markov model through the average duration of a pairing with a SERV or EMOT of 7 years in total (inclusive of the 18 month duration of the trial and 5.5 additional years).[64-66] Limited high-quality evidence exists surrounding the average duration of dog and Veteran pairing. Given cited ranges such as 7 to 10 years for SERV pairings, we opted to select the lower end of this range of 7 years to account for potential discontinuation of dog and Veteran pairings while also exploring the robustness of the dog pairing duration through sensitivity analyses. The forecasting assumption, without evidence of temporal trends or interactions, was that any clinical benefits or health system payer costs observed in the trial follow-up were carried forward at the same level through the average duration of the dog pairing (i.e., 7 years from pairing).

We included one dog and Veteran pairing in our primary analysis. Given an absence of evidence, no clinical benefits or costs associated with the dog pairing were assigned beyond the duration of the dog and Veteran pairing. In the primary analysis, the incremental cost-effectiveness findings would be the same for a time horizon equal to that of the duration of the dog pairing (i.e., 7 years from pairing) or a lifetime time horizon that is consistent with best practices. Differences in incremental cost-effectiveness findings from a 7-year versus lifetime time horizon would occur when 1) evidence suggests a progressive disease state and an intervention that changed the trajectory of disease progression or, 2) Veteran survival is different between the SERV intervention and the EMOT intervention by or before the end of the dog pairing horizon. Neither of these scenarios are supported by current evidence. To follow best practices, we continued to use the two-state Markov model after the dog pairing duration to forecast a lifetime time horizon for Veterans, assuming PTSD usual care.

We used a two-state (alive and dead) Markov model with annual cycles to implement the forecasting and conversion of the VA trial outcomes into the findings needed to estimate lifetime incremental cost effectiveness. Patients can transition to the dead health state due to all-cause mortality with adjustments made for increased probability of death among those with PTSD. All patients who do not transition to the dead health state remain in the alive health state. After preliminary review of the VA trial findings and discussion with stakeholders, we determined that there was not sufficient evidence to suggest impacts on mortality for the SERV intervention compared to the EMOT intervention; thus, transitions from the alive to dead health state were assumed the same between intervention arms. Within the alive health state, economic and clinical outcome differences between intervention arms were tracked and conditioned on each intervention. The VA trial findings suggest no time effects (e.g. no attenuation, modification or increases over time) on the measures used to estimate cost-effectiveness.[1,18,61] Therefore, the cost-effectiveness findings produced by more complex (three-state or higher) Markov model structures would result in the same findings compared to a more simple two-state Markov model that is conditioned on intervention.

Figure 2.4.1. Cost-Effectiveness Model Structure



PCL-5: PTSD Civilian Checklist 5, VA: United States Department of Veterans Affairs

2.4.4 Key Model Assumptions and Inputs

We made key choices and assumptions listed in Table 2.4.1 to achieve our study objective. As summarized in Section 2.1.3, the VA trial findings formed the foundation of the cost-effectiveness analyses. Key model choices included what clinical outcomes from the trial formed the basis for estimating effectiveness in terms of quality-of-life utilities for use in the cost-effectiveness analyses. Peer-reviewed literature suggests that two instruments measured in the VA Trial were previously associated with utility weights: the Veterans RAND 12 Item Health Survey (VR-12) instrument[67] and the PCL-5 instrument.[68] Following ICER's reference case and Value Assessment Framework[62] as well as other health technology assessment best practices,[63] generic measures that reflect community preferences are preferred. However, in cases where generic instruments are deemed not sensitive enough to detect a difference, disease-specific instruments may be used. VR-12 is a generic instrument, and the PCL-5 instrument is the only disease-specific instrument in the VA trial that captured changes in PTSD symptoms and that is associated with utility weights. When comparing the SERV intervention to the EMOT intervention, there was a statistically significant difference observed in the PCL-5 and no statistical difference observed in the VR-12. After consultation with clinical experts, we decided to use the statistically significant difference observed in the PCL-5 for the purposes of estimating cost-effectiveness. Our decision is consistent with a conclusion that the VR-12 may not be sensitive enough to detect PTSD symptom changes in this context. We included a scenario analysis using the VR-12 trial findings to estimate quality-of-life utilities for the purposes of characterizing structural uncertainty in this key model choice and corresponding input (See Scenario Analyses 2.4.5). Finally, we note that the cost-effectiveness analysis plans happened after

preliminary findings from monograph 1 were known. Thus, the cost-effectiveness analyses used post hoc methods of analysis.

The Effectiveness Outcomes section details other evidence-based decisions such as assuming no differences in mortality across interventions.

Table 2.4.1. Key Model Choices and Assumptions

Model Choice or Assumption	Rationale
Observed VA trial findings[1,18,61] formed the foundation for the cost-effectiveness analyses.	No other randomized evidence source compares the clinical or economic outcomes of SERV intervention versus EMOT intervention or versus no dogs for Veterans with PTSD.
We assumed the clinical benefits or costs observed during the trial duration[1,18,61] were carried forward at the same level through the average duration of the dog pairing.	In the absence of evidence suggesting time trends associated with an outcome, the observed mental health outcomes and health care costs were assigned through the remaining years of the dog/Veteran pairing. We adjusted for average population survival and annualized discounting using standard practices (i.e., annual cycle Markov model).
Modeling subsequent dog pairings would result in consistent incremental cost-effectiveness findings as compared to the primary analysis that does not model subsequent dog pairings so long as intervention time trends and survival differences are not observed.	Given current evidence, the primary analysis findings may be interpreted as the cost-effectiveness of pairing a highly trained SERV to a Veteran with PTSD no matter the Veteran's prior history or plans for future dog pairings.
Discontinuation of the dog and Veteran pairing was accounted for in the average pairing duration.	The impacts of discontinuation were explored through varying the duration of the dog and Veteran pairing.
We included a supporting threshold analysis that assumed the current VA payer perspective of only including the annual insurance costs (not the procurement or pairing costs) of the SERV intervention to estimate health gains needed to achieve cost effectiveness versus usual care (no dog)	VA decision makers are interested in the relative effectiveness and cost-effectiveness of SERVs when compared to usual care without a dog, from a VA payer perspective (the current VA policies suggest not paying for the procurement or pairing of a SERV, but are considering paying for the annual SERV insurance through the time horizon of a pairing). [1,18,61]Due to weaknesses in the quality of evidence, we report the health gains needed to achieve cost-effectiveness when assuming no cost savings of SERV versus no dog.

EMOT: Emotional support dog, PTSD: post-traumatic stress disorder, SERV: Service Dog, VA: United States Department of Veterans Affairs

The population of focus for the cost-effectiveness analysis consisted of US Veterans age 18 years or older with a diagnosis of PTSD. Table 2.4.2 provides the baseline population characteristics for the analysis that mirrored the population characteristics from the VA trial.[1,61] Characteristics that

directly flowed into the cost-effectiveness analysis included age and gender for estimating annual survival. Other characteristics aid in the interpretation and generalizability of the findings.

Table 2.4.2. Baseline Population Characteristics

Population Characteristics	Value	Notes/Source
Mean age (years)	50.6	VA trial [1,61]
Female (%)	20%	VA trial[1,61]
Hearing Impairment (%)	47%	VA trial[1,61]
Visual Impairment (%)	18%	VA trial[1,61]
Mobility Impairment (%)	35%	VA trial[1,61]
Employed part or full time (%)	28%	VA trial[1,61]

VA: United States Department of Veterans Affairs

Table 2.4.3 features the key model inputs across effectiveness and cost.

Effectiveness Outcomes

We used the QALY as the primary measure of effectiveness in estimating the cost-effectiveness of the SERV intervention versus the EMOT intervention. The QALY is comprised of two main components: 1) mortality (or survival) that comprise the life year component and 2) quality-of-life utilities that comprise the quality adjusted or morbidity component. A one-unit improvement in the PTSD symptom measure, the PTSD Civilian Checklist 5 (PCL-5) acted as a supporting clinical measure of effectiveness.

Mortality

No differences were observed in suicide or mortality over the 18-month VA Trial. [1,61] Although not consistent across time, an analysis suggested fewer suicidal thoughts at the 18-month trial timepoint within the SERV intervention versus the EMOT intervention cohort. [1,61] We assumed no differences in mortality between any of the pairwise intervention comparisons. If differences in suicidal thoughts were shown to translate into differences in all-cause mortality, then our assumption would be considered conservative in terms of the incremental effectiveness of the SERV intervention. We applied the same PTSD standardized mortality ratio to US age-matched all-cause mortality for the intervention and comparator to forecast the lifetime time horizon. We used the PTSD standardized mortality of 1.05 (95% CI: 1.02–1.08) based on a study of US Veterans with PTSD.[69] We sourced the all-cause gender- and age-specific mortality from the US Social Security Administration.[70]

Quality-of-Life Utilities

We used VA trial changes in the PCL-5 instrument that were associated with changes in quality-of-life utility weights as detailed in Freed et al.[68] Briefly, Freed and colleagues measured the PCL-4 and the Medical Outcomes Survey Short Form-36 (SF-36) in 808 US Veterans. The SF-36 is a generic instrument that has published utility weights based on previous community-based trade-off exercises in the United Kingdom.[71] Freed et al. fit regression models using the SF-36 derived utility score outcome to determine if Veterans with different PCL-4 scores had different predicted utility scores. Freed and colleagues found that for every point increase in PCL score (lower scores suggest fewer or less PTSD symptoms), resulted in a -0.0038 change in utility weights (p-value < 0.01). The Freed et al. study included a subset of Veterans with PTSD. Therefore, we applied the PTSD-specific change in utility weights of -0.002 per unit increase in the PCL score (p-value < 0.01). Compared to the Veterans with PTSD subset, the overall estimate from the study of 808 Veterans suggesting a utility weight of -0.0038 per unit increase in the PCL-4 yields higher incremental QALY gains for interventions that show sustained changes in the PCL-4 instrument.

The VA Trial used PCL-5 whereas the Freed et al. study used PCL-4. Given the large overlap in the 17 items used in PCL-4 (score range from 17 to 85) with the 20 items used in PCL-5 (score range of 0 to 80), we assumed a linear relationship of every one point change in the PCL-5 is equal to a (85 -17) / (80 – 0) = 0.85 point change in the PCL-4 instrument. This assumption was supported by K. Magruder (personal communication, September 2020) who has a longstanding track record of funding and peer-reviewed research with the PCL-4 and PCL-5 instruments. We acknowledge that this mapping between PCL-4 and PCL-5 was ad hoc and was conducted during the model analysis planning phase of this work.

To derive the best-available estimate of a utility weight difference between SERVs and EMOTs, we used the difference in PCL-5 instrument from the VA Trial multiplied by the PCL adjustment (from 5 to 4) multiplied by the utility weight per unit increase in the PCL-4 = -3.7 * 0.85 * -0.002 = 0.0063. The uncertainty, including lower and upper bounds of the 95% confidence interval and corresponding normal distribution with mean -3.7 and standard error of 1.75 in the PCL-5 instrument group difference, and the uncertainty in the utility score mapping, was propagated through in estimating the uncertainty in utility weight difference between SERVs and EMOTs.

Other measures of effectiveness from the VA Trial such as increases in proportion of days covered for antidepressants or antipsychotics were not mapped to a utility weight in the primary analysis given concerns about potential correlation with other non-statistically significant measures in the trial (e.g., Patient Health Questionnaire [PHQ-9] and Dimensions of Anger Reactions (DAR) as well as no known mapping algorithm between higher proportion of days covered and utility scores. This implies that all benefits gained from having a service dog manifest direct from the PCL-5.

Cost Outcomes

All costs used in the model were adjusted to approximate the present value (2018 US Dollars) through inflation and discounting.[72] Consistent with ICER's reference case, we discounted future costs and outcomes within the model using the annual discount rate of 3% per year. All cost inputs from the economic trial evaluation (Chapter 1) were inflated to 2018 US Dollars. The cost inputs consist of the intervention costs and the healthcare utilization costs associated with PTSD and each dog intervention type.

Intervention Costs

The average time to pairing for those randomized to EMOT was 158 days whereas the average time to pairing for those randomized to SERV was also 158 days. A paired t-test p-value was 0.99 assuming unequal variances between the EMOT and SERV average time to pairing. No cost differences related to time to pairing were assumed for the SERV versus EMOT comparison.

We used findings from the VA Trial budget as the best proxy estimate for the cost of procuring, pairing, and insuring a SERV and an EMOT. The bundled procurement and pairing costs (SERV = $25,680; EMOT = $15,858) are one-time whereas the annual insurance costs ($2,665 for SERV and for EMOT) were applied to all years through the duration of the dog and Veteran pairing (i.e., 7 years). See Supplement Table 2.A2 for itemized costs within the bundled procurement and pairing estimates. Note that the bundled procurement and pairing costs included the time spent by dog trainers.

Health Care Utilization Costs

The VA Trial suggested no observed differences in health care utilization costs from the VA or non-VA perspectives. Therefore, we have no evidence to suggest health care utilization costs differ between SERVs and EMOTs. Based on one year of data available prior to randomization, $21,522 in annual health care costs were associated with Veterans with PTSD who were subsequently randomized to the EMOT group; this annual cost of $21,522 was included as the baseline annualized health care costs across the SERV and EMOT interventions. To model an increase in health care costs as one ages, we applied an annual cost multiplier by fitting an exponential distribution to average age-adjusted healthcare costs that included personal health care spending paid for by private health insurance, Medicare, Medicaid, out-of-pocket payments, and all other payers and programs.[73] These multipliers were calculated using a baseline age of 50 given the model start age of 50. As age increased in the model, the annual health care costs were adjusted by the multiplier. [73]For example, the annualized health care cost multiplier was 1.53 by age 65.

Productivity and Employment Costs

The VA Trial suggested no observed differences in work productivity or employment. Therefore, we have no evidence to suggest these costs differ between the SERV and EMOT interventions.

Lifetime Time Horizon

Beyond the time horizon of the Veteran and dog pairing, we assigned no difference in costs or outcomes across the intervention and comparator groups except for when survival difference scenarios were modeled prior to the end of the Veteran dog pairing. To estimate lifetime time horizons of the Veteran, we applied average PTSD-associated annualized health care costs, utilities, and survival to both the intervention and comparator groups.

Table 2.4.3. Key Model Inputs

Parameter	Input	Uncertainty	Source
Key Effectiveness Inputs			
VA Trial PCL-5 (SERV vs. EMOT)	3.7 point improvement	Normal (mean = 3.7; SE = 1.75)	SERVs reduced PCL-5 measured PTSD symptoms by 3.7 points, on average.[1]
PCL-5 to PCL-4	1 (PCL-5) point = 0.85 (PCL-4) points	Uncertainty from changes in PCL-5 propagated through to PCL-4	Expert opinion suggested linear relationship between two PCL versions.
PCL-4 Change to utility weights	Primary Analysis: (From PTSD VA Subset): 1 (PCL-4) point = -0.002 utility weight	Alternative (based on overall VA population): 1 (PCL-4) point = -0.0038 utility weight	Worsening PCL-4 symptoms (increases in score) resulted in worsening utility weights.[68]
Key Cost Inputs			
Annual Baseline Medical Costs	$21,522	N/A	Mean annualized health care costs from the EMOT intervention in the pre-trial period.[18] This annualized estimate was applied to all interventions and across all model years. A multiplier was applied as the cohort aged (see Health Care Utilization Costs text).
Procurement and successful pairing of SERV	$25,680	Normal (mean = $25680; SE = 20% of the mean)	Consistent with paid amounts for dog vendor and associated Veteran pairing costs
Procurement and successful pairing of EMOT	$15,858	Normal (mean = $15858; SE = 20% of the mean)	Consistent with paid amounts for dog vendor and associated Veteran pairing costs

Annual insurance cost for SERV or EMOT dogs	$2,665	Normal (mean =$2665; SE = 20% of the mean)	Consistent with paid amounts for dog insurance within the VA trial
Difference in annual total health care total (SERV vs. EMOT)	$0	N/A	No statistical differences were observed for SERV vs. EMOT.[18]
Difference in annual productivity-related costs (SERV vs. EMOT)	$0	N/A	No statistical differences were observed for SERV vs. EMOT.[18]
Model Wide Inputs			
Duration of Veteran and dog pairing	7 years[65,66]	Normal (mean = 7; SE = 1)	Both SERVs and EMOTs assumed to be paired for an average of 7 years with an approximate 95% interval between 5 and 9 years.[64]
PTSD standardized mortality ratio	SMR = 1.05 (95% CI: 1.02–1.08)	Normal (mean = 1.05; SE = 0.03)	PTSD mortality will be assigned to SERV, EMOT and no dogs[69]
All-cause gender- and age-specific mortality	Appendix Table 2.A3.	N/A	Social Security Administration Actuarial Life Table[70]
Annualized discount rate for costs and outcomes	3% per year	N/A	ICER Value Assessment Framework and US HTA best practice guidelines[62,63]

EMOT: Emotional support dog, HTA: health technology assessment, ICER: Institute for Clinical and Economic Review, N/A: not applicable, PCL-4: PTSD Civilian Checklist 4, PCL-5: PTSD Civilian Checklist 5, PTSD: post-traumatic stress disorder, VA: United States Department of Veterans Affairs, SERV: Service dog, SMR: standardized mortality ratio

2.4.5 Model Analyses

For the primary analysis, we estimated the health system payer perspective incremental cost per QALY by taking the difference in lifetime mean costs for SERV versus EMOT groups and dividing by the difference in lifetime mean QALYs for individuals in the SERV and EMOT groups. The prices needed to meet common cost-effectiveness thresholds were estimated by multiplying the difference in lifetime mean QALYs by commonly cited thresholds (e.g., $100,000/QALY). Groundbreaking research from both the demand and supply side of eliciting health thresholds continues to support the commonly cited threshold of $100,000 per QALY gained as a guide to

assessing the appropriate top end of cost-effectiveness of new health technologies in the US.[74,75] Given the pluralistic US health system, however, ICER continues to report a range of thresholds to aid decision making. We compare this monetized health gain to that of the difference in lifetime mean costs. Finally, we solve for the maximum bundled price of SERVs that achieves a difference in lifetime mean costs equal to (and no greater than) the monetized improvements in health. This process is repeated for each price benchmark.

Sensitivity Analyses

We conducted one-way sensitivity analyses to identify the impact of parameter uncertainty and key drivers of model outcomes. We presented the findings visually through a tornado diagram that depicted the influence of variations in key inputs on cost effectiveness. Probabilistic sensitivity analyses were performed by jointly varying all uncertain model parameters over 1,000 simulations. We presented the findings as the proportion of simulations that achieved various price benchmarks ($50,000/QALY through $200,000/QALY) and using a cost-effectiveness acceptability curve.

Scenario Analyses

We conducted additional scenario analyses assuming the primary comprehensive health system payer perspective (including procurement and insurance costs; versus the EMOT intervention) unless otherwise specified:

- Societal perspective incremental cost inputs included those costs featured in the health system (government payer) perspective as well as the monetization of participant pairing time and the potential for differences in participant work hours. The trial suggested no statistical differences in productivity or employment costs. Further, no statistical differences were observed in the wait time between randomization and pairing for the SERV and EMOT randomization cohorts. However, trends in Chapter 1 analyses suggest that SERV may increase participant work hours when compared to EMOT. Therefore, we conducted a threshold analysis by first assuming that SERV was associated with 40 additional hours of participant-time around the time of pairing (versus EMOT). This assumed additional participant-time for those paired with SERV was not measured in the trial and should be interpreted as a placeholder value. We applied the median hourly wage of $27.07 to potentially increase the participant-time costs for SERV vs. EMOT (one-time increase of 40 * $27.07 = $1082.80). Then, we solved for the increased average number of work hours (SERV vs. EMOT) that would be required to produce cost savings (valued at - $27.07 per hour of added work) over the course of the seven-year pairing for SERV to meet commonly cited cost-effectiveness thresholds ($50,000/QALY, $100,000/QALY, and $150,000/QALY). We were unable to find evidence on any of the other cost domains from the social perspective including: patient out of pocket costs, future unrelated medical costs, caregiver costs, transportation costs (other than related to the SERV dog pairing), consumption costs,

social services costs, legal/criminal costs, education costs, housing costs, environment costs or other. We provided comment on the potential impact of these missing cost domains within the section 2.4.7.

- Primary cost-effectiveness analysis by time horizon year that displays the discounted incremental cost-effectiveness of SERV versus EMOT by time (years).

- Alternative quality-of-life utility estimation using the trial findings from the difference in VA-12 physical and mental health scores. The adjusted trial findings over time from monograph 1 suggest VA-12 physical health summary scores were 0.9257 higher (95% CI: -1.3379, 3.1893) and suggest VA-12 mental health summary scores were 0.5798 (95% CI: -1.6341, 2.7938). [1 (p92)] Literature suggests a mapping from average trial effects of the VA-12 to quality-of-life utility scores that results in a deterministic improvement in utility of 0.0041 per unit of time (when paired with SERV vs. EMOT).[67,76] In contrast, the base-case PCL-5 mapping results in an improvement in utility of 0.0063.

- Threshold break-even scenarios evaluating the quality-of-life utility gains (including alternative utility estimate per unit change in PCL-4), survival gains, and cost-offsets needed to achieve the commonly cited cost-effectiveness benchmark of $100,000 per QALY gained.

- Alternative mapping of the PCL-5 to a quality-of-life based utility.

- Threshold price analysis where the SERV costs are compared to a range of cost-effectiveness benchmarks ($50,000/QALY, $100,000/QALY and $150,000/QALY gained).

Finally, we conducted the following VA payer threshold scenario from the current VA payer perspective (SERV insurance costs only; SERV comparison versus no dog to identify the health gains needed to achieve the commonly cited cost-effectiveness benchmark of $100,000 per QALY gained):

- A threshold analysis of SERV versus no dog (usual care) for Veterans with PTSD assuming the current VA payer perspective. This comparison assumed only the annual insurance costs of $2,665 for the duration of the SERV pairing but no procurement or pairing costs. Further, no potential cost-savings were assumed to SERV versus no dog. In this threshold analysis, we solved for the average change in PCL-5 needed to achieve an incremental cost-effectiveness of $100,000 per QALY gained. As an alternative, we also provided the average change in VA-12 physical health summary score and mental health summary score needed to achieve an incremental cost-effectiveness of $100,000 per QALY. We did not assume any evidence from the pre-post trial analyses in conducting this threshold analysis. Given the current evidence, if anything, we presume this threshold analysis to be biased against SERV achieving cost effectiveness. This presumption is due to the potential for SERV to be associated with cost offsets or health improvements not captured within this threshold

analysis. For reference, the adjusted average change in PCL-5 was -3.7 (SERV vs. EMOT) and the unadjusted change in PCL-5 was -11.7 (post EMOT at 18 months vs. pre EMOT). Thorough comparative-effectiveness and cost-effectiveness research remains needed to comprehensively evaluate the SERV versus no dog comparison.

Model Validation

We used several approaches to validate the model. First, we presented our model analysis plan to health economics and veterinary experts from the VA. Based on feedback, we refined data inputs used in the model, as needed. Second, we varied model input parameters to evaluate face validity of changes in results. We performed model verification for model calculations using internal reviewers. We updated the analyses and this report based on the feedback from The National Academies of Sciences, Engineering, and Medicine. Finally, the outputs from the model were compared against the trial/study data of the interventions and any other relevant sources.

2.4.6 Results

Comprehensive Health System Payer (including procurement and insurance costs; versus the EMOT intervention) Primary Results:

The primary analysis lifetime discounted results showed that SERV procurement and pairing costs totaled $25,680 versus $15,858 for EMOT, with both types of dog requiring an additional insurance cost of $16,798 over the average seven-year pairing duration. The average PTSD non-intervention lifetime costs were $600,578 for the SERV and EMOT interventions. The incremental lifetime discounted costs for SERV vs. EMOT were $9,822 (95% interval: -$4,700 to $24,400). The potential health gains observed by an improvement in PCL- 5 for SERV of 3.7 units resulted in no differences in life years but 0.039 quality-adjusted life years gained (Table 2.4.4) (95% interval: -0.0006 to 0.1074). Equal value of life years gained is not presented given identical findings to that of the QALY.

Table 2.4.4. Primary Analysis Lifetime Discounted Deterministic Results (SERV Compared to EMOT)

Treatment	Dog Pairing and Insurance Cost	PTSD Non-Intervention Lifetime Costs	Total Health System Payer Cost	Life Years	QALYs*	PCL- 5 (average score over dog pairing)
SERV	$42,478	$600,578	$643,056	18.635	10.786	31.55
EMOT	$32,656	$600,578	$633,234	18.635	10.747	35.25
Incremental (SERV – EMOT)	$9,822	$0	$9,822	0.000	0.039	-3.7†

EMOT: Emotional support dog, PCL- 5: PTSD Civilian Checklist 5, PTSD: post-traumatic stress disorder, QALY: quality-adjusted life year, SERV: Service dog

* Equal value of life years gained were identical to incremental QALYs and therefore were not displayed.
† Negative values for the incremental PCL- 5 suggests improvements in PTSD symptoms (SERV vs. EMOT)

The incremental cost-effectiveness ratio comparing SERV to EMOT is approximately $249,000 per QALY gained (Table 2.4.5). Uncertainty in the incremental cost-effectiveness ratio is characterized by way of sensitivity analyses given the challenges in interpreting negative incremental cost-effectiveness ratios. Incremental cost per life-year gained is not displayed given no differences in life-years gained. The added costs a government payer would anticipate spending for SERV pairing to achieve an improvement of one unit in the PCL-5 is $2,655.

Table 2.4.5. Primary Analysis Incremental Cost-Effectiveness Ratios (SERV Compared to EMOT)

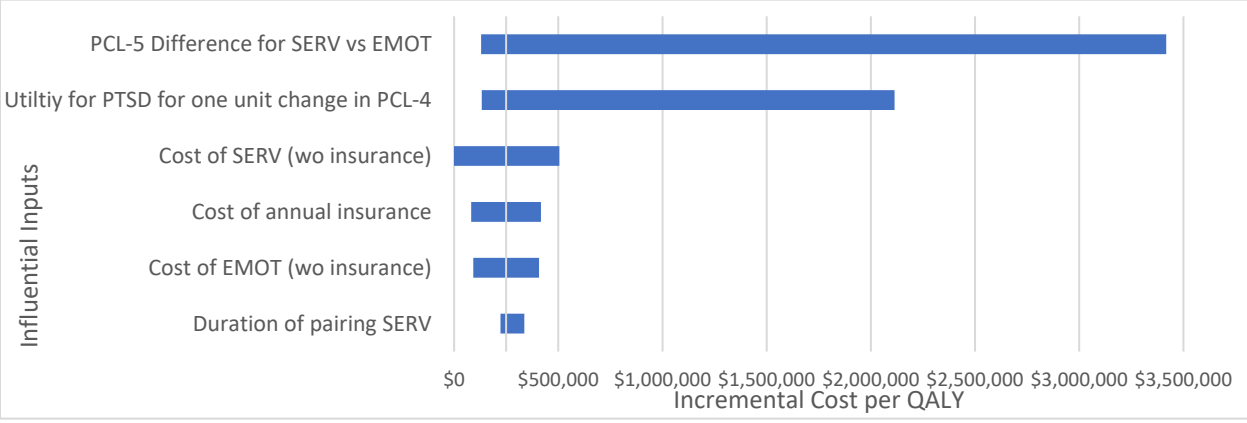
Treatment	Cost per QALY Gained	Cost per unit improvement in PCL-5
SERV vs. EMOT	$249,000	$2,655

EMOT: Emotional support dog, PCL- 5: PTSD Civilian Checklist 5, QALY: quality-adjusted life year, SERV: Service dog

Sensitivity Analyses

Figure 2.4.2 displays the one-way sensitivity analyses from the primary analysis SERV vs. EMOT group comparison. Influential inputs are rank-ordered from top to bottom. The most influential input was the 3.7 unit improvement in PCL-5 with its corresponding 95% confidence interval ranging from 0.3 to 7.1. Replacing the 3.7 unit improvement with the lower (0.3) and upper (7.1) bounds of the 95% confidence interval resulted in incremental findings that ranged from $3,417,000/QALY to $129,000/QALY, respectively. The utility mapping from the PCL instrument was also an influential input with incremental findings ranging from $133,000/QALY to $2,113,000/QALY. Varying the duration of pairing between 5 years and 9 years resulted in incremental findings that ranged from $337,000/QALY to $222,000/QALY, respectively.

Figure 2.4.2. Tornado Diagram: One-Way Sensitivity Analyses for Primary Analysis (SERV vs. EMOT)



EMOT: Emotional support dog, PCL-4: PTSD Civilian Checklist 4, PCL- 5: PTSD Civilian Checklist 5, PTSD: post-traumatic stress disorder, SERV: Service dog, wo: without

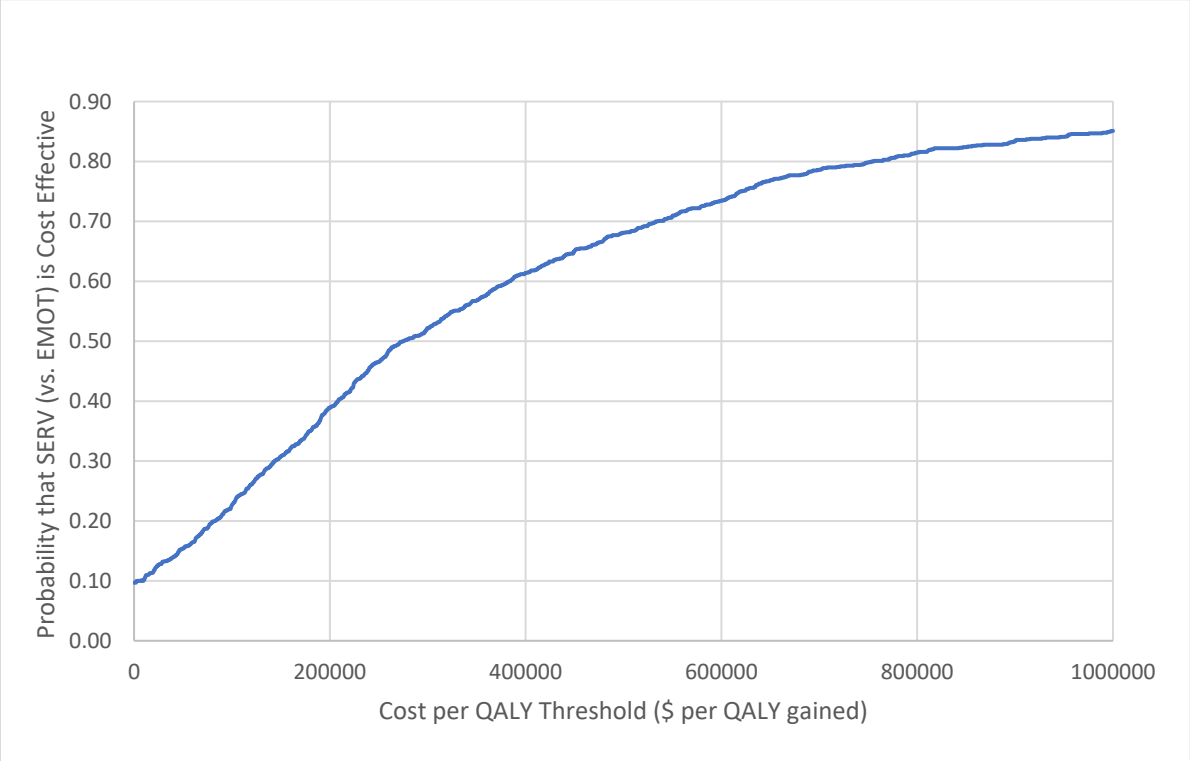
Table 2.4.6 presents the probabilistic sensitivity analyses in terms of the probability that SERV is the favored intervention of common cost-effectiveness benchmarks. At the highest included cost-effectiveness benchmark of $200,000/QALY, the probability that SERV was cost-effective was 38.9%. Figure 2.4.3 presents the cost-effectiveness acceptability curve and gives further granularity to the tabular presentation on the probability that SERV is cost effective across a range of cost per QALY thresholds.

Table 2.4.6. Probabilistic Sensitivity Analysis Cost per QALY Gained Results: SERV versus EMOT

	Cost Effective at $50,000 per QALY	Cost Effective at $100,000 per QALY	Cost Effective at $150,000 per QALY	Cost Effective at $200,000 per QALY
SERV vs. EMOT	15.4%	22.7%	30.8%	38.9%

EMOT: Emotional support dog, QALY: quality-adjusted life year, SERV: Service dog

Figure 2.4.3. Cost-Effectiveness Acceptability Curve: Probability that SERV is Cost Effective by Cost per QALY Thresholds



EMOT: Emotional support dog, QALY: quality-adjusted life year, SERV: Service dog

Scenario Analyses (including procurement and insurance costs; versus the EMOT intervention)

Societal Perspective

The societal perspective included all costs from the comprehensive health care payer perspective plus a placeholder value for added participant time spent during the SERV pairing (versus EMOT). We then solved for the number of increased weekly work hours (SERV versus EMOT) needed to produce cost savings to reach commonly cited thresholds.

The incremental cost-effectiveness of SERV versus EMOT when adding the placeholder 40-hour increase in participant time was $277,000/QALY. When solving for the average number of increased work hours per week and assuming that the increased number of work hours was sustained over the course of the seven-year dog pairing (SERV vs. EMOT), the average weekly work hours ranged between 1.0 and 0.6 hours to reach threshold ranges of $50,000 per QALY to $150,000 per QALY gained (Table 2.4.7). When solving for the average number of increased work hours per week and assuming that the increased number of work hours was only to apply during the course of the 18-month trial (SERV vs. EMOT), the average weekly work hours ranged between 2.4 and 4.3 hours to reach threshold ranges of $50,000 per QALY to $150,000 per QALY gained.

As presented in Chapter 1 (Table 1.6), there was no statistically significant difference in weekly work hours (SERV vs. EMOT), but the point estimate of 5.30 (95% CI: -1.12 to 11.72) hours trended toward increases for SERV. If the point estimate of 5.30 weekly hours was assigned across at least the duration of the 18-month trial, the societal perspective average incremental cost-effectiveness findings would be lower than $50,000 per QALY gained.

Table 2.4.7. Societal Perspective Scenario Analysis on Increased Number of Weekly Work Hours Needed to Achieve Commonly Cited Cost-Effectiveness Thresholds

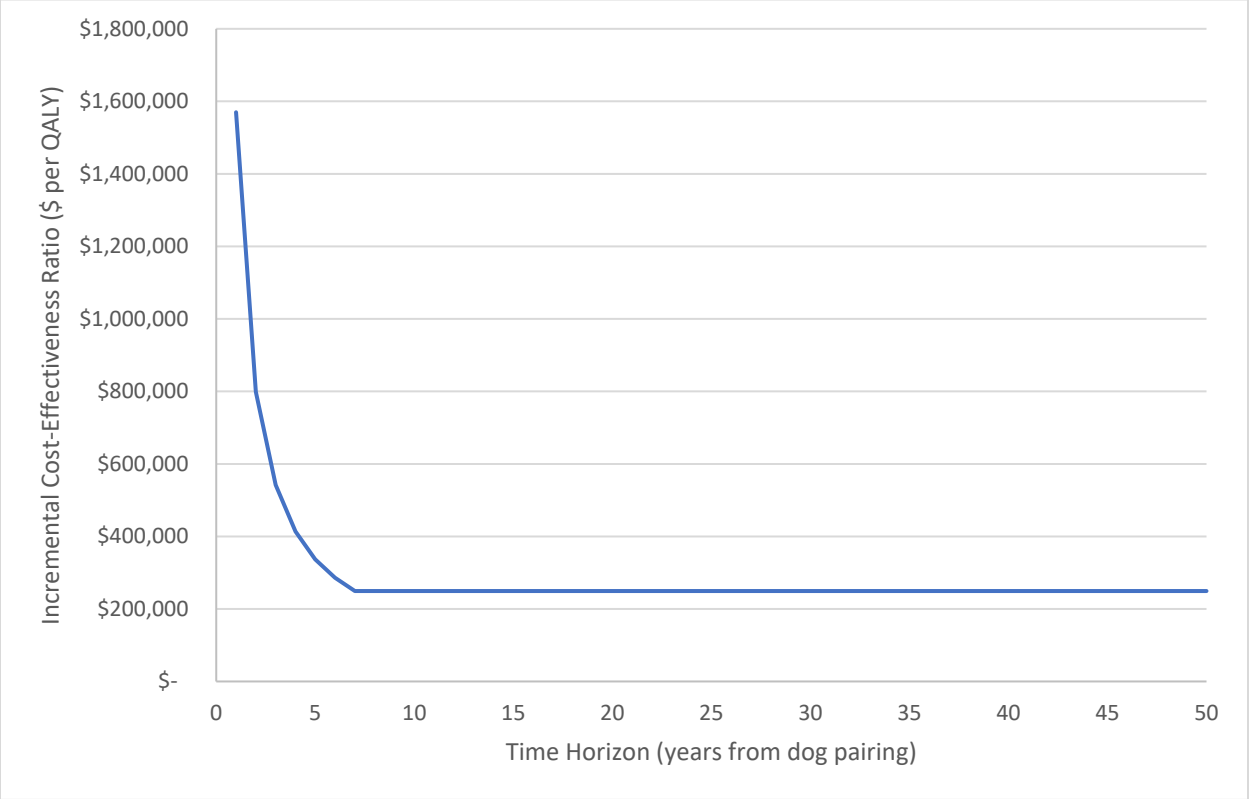
	Weekly Increase in Work Hours to Achieve $50,000 per QALY	Weekly Increase in Work Hours to Achieve $100,000 per QALY	Weekly Increase in Work Hours to Achieve $150,000 per QALY
Societal Perspective Scenario: SERV (vs. EMOT) for Seven Year Dog Pairing Duration	1.0 hour per week	0.8 hours per week	0.6 hours per week
Societal Perspective Scenario: SERV (vs. EMOT) for 18-Month Duration Only	4.3 hour per week	3.4 hours per week	2.4 hours per week

EMOT: Emotional support dog, QALY: quality-adjusted life year, SERV: Service dog

Incremental Cost-Effectiveness by Time

Figure 2.4.4 presents the discounted incremental cost-effectiveness findings (SERV vs. EMOT) by time (years from dog pairing). Given the costs of the SERV and EMOT interventions are accrued in the first year of the analysis whereas the added health was assumed to accrue at the same rate over the dog pairing of seven years, the incremental cost-effectiveness of SERV versus EMOT is over $1 Million per QALY gained in the first year and stabilizes at the lifetime deterministic finding of $249,000 per QALY gained after seven years from the dog pairing.

Figure 2.4.4. Discounted Incremental Cost Effectiveness of SERV versus EMOT over Time (years from dog pairing)



QALY: quality-adjusted life year

Alternative Utility Estimation using the VA-12

The potential health gains observed from the deterministic differences in the VA-12 that favored SERV but were not statistically significant resulted in no differences in life years but 0.026 quality-adjusted life years gained (versus 0.39 QALYs gained using the PCL-5 instrument). The incremental costs remain unchanged at $9,822. The incremental cost-effectiveness ratio comparing SERV to EMOT by way of the VA-12 mapping into utilities is approximately $385,000 per QALY gained.

Model input scenarios to reach $100,000/QALY threshold

Scenarios with variations in key inputs were generated to suggest threshold changes in key model inputs that would be needed to achieve an incremental cost-effectiveness ratio of $100,000/QALY gained for the SERV vs. EMOT interventions:

- A 9.3 PCL-5 unit improvement instead of a 3.7 PCL-5 unit improvement
- A hazard ratio for mortality of 0.86 over the course of the pairing duration instead of no difference in mortality (hazard ratio of 1.00)
- An annual reduction of $935 in health care utilization over the course of the pairing duration instead of no health care annual cost differences

Alternative PCL-5 utility mapping

Finally, we estimated the incremental cost per QALY based on an alternative (and more favorable) mapping between the PCL instrument and quality-of-life based utilities. Instead of assigning a one unit improvement in the PCL-4 instrument to a 0.002 unit increase in utilities, if we assign a 0.0038 unit increase in utilities, as observed in the overall VA population (not only the PTSD subpopulation[68]), the incremental cost-effectiveness was $131,000/QALY.

Threshold Price Analyses

The bundled price of SERV procurement, pairing, and insurance through the pairing duration to achieve commonly cited cost-effectiveness thresholds are presented in Table 2.4.8. SERV procurement and pairing costs totaled $25,680 whereas insurance costs over the duration of an average seven-year pairing were $16,798 at present value. In the primary analysis, to achieve a bundled price including insurance costs that meets the $100,000 per QALY gained benchmark, the price across procurement, pairing, and insurance should be no greater than $36,498. A reduction of at least $5,980 (14% off current pricing) would be required to achieve the $100,000 per QALY gained benchmark. This reduction of at least $5,980 could be applied to the procurement and pairing costs of $25,680 (resulting in a value-based price for procurement and pairing of no more than $19,700) or to the average seven-year insurance costs of $16,798 (resulting in a value-based price for seven-year insurance of no more than $10,818), or to a combination of the two (e.g., at least a 14% reduction to both price components).

Table 2.4.8. Threshold Price Analysis Results

	Bundled price including pairing and insurance	Unit Price to Achieve $50,000 per QALY (% Discount from bundled price)	Unit Price to Achieve $100,000 per QALY (% Discount from bundled price)	Unit Price to Achieve $150,000 per QALY (% Discount from bundled price)
Comprehensive Health System Payer Primary Analysis: SERV (vs. EMOT)	$42,478 (including pairing and insurance)	$34,598 (19%)	$36,498 (14%)	$38,498 (9%)

EMOT: Emotional support dog, QALY: quality-adjusted life year, SERV: Service dog

VA Payer Perspective Threshold Health Improvement Analyses (SERV insurance costs only; comparison versus no dog)

The SERV intervention annual insurance costs over an average seven-year pairing resulted in $16,798 (present value). When assuming no potential cost savings due to SERV versus no dog and assuming a cost-effectiveness threshold of $100,000 per QALY gained, the incremental utility improvement needed for SERV to be cost effective was 0.027 over the entire seven-year dog pairing duration. We translated the 0.027 utility improvement into changes in the PCL-5 using the same method as described in the primary analysis and yielded -15.8 units in the PCL-5 total score where smaller scores suggest improved PTSD symptoms. Alternatively, we translated the 0.027 utility improvement into changes in the VA-12 using the same method as described in the scenario analysis and yielded 6.1 unit improvement in the physical health summary score and 3.8 unit improvement in the mental health summary score.

2.4.7 Uncertainty and Controversies

We acknowledge that VA's efforts to reduce data variability through contract requirements may have come at the expense of the study findings being generalizability to real world conditions, as discussed on pages 42-43. For example, the VA contract specified that sporting breeds (retrievers and retriever crosses) and German Shepherds be used for both types of dogs because of their trainability and pleasing temperament; these breeds are most commonly used by reputable service dog organizations.[77] The study service dogs and emotional support dogs were obedience trained as a safety precaution; VA developed its own training standards for both dog types based on consultation with subject matter experts. In contrast, the average emotional support dog may be a stray or relinquished pet adopted from a shelter or possibly even from a breeder. There is no requirement for emotional support dogs to be obedience trained; although, some owners elect to do so. As noted previously, unacceptable emotional support animal behavior became a public safety issue that prompted the DOT to rule that they are pets and most be secured in kennels when

traveling with their owners aboard commercial aircraft.[78] Socialization and obedience training are considered basic steps to minimizing the risk of dog bites and behavioral problems that may result in the pet being relinquished by the owner.[79,80] The contract standards developed by VA were instrumental in ensuring study participants received a healthy well-behaved dog, which helped to encourage a strong and lasting bond between the Veteran and their dog.

We note several limitations to the cost-effectiveness analysis. First, the VA trial did not achieve statistically significant differences on its co-primary outcome measures. Given the currently available evidence, decision makers should first wrestle with whether SERVs paired to Veterans with PTSD supports at least comparable if not positive net health benefits as compared to its alternatives. Second, unlike pharmaceutical interventions, each VA trial SERV is unique. In the VA trial, each SERV was trained to perform the same five tasks, but SERVs in the real world may be more tailored to the needs of individual Veterans. Therefore, the reproducibility of SERVs beyond this trial and uncertainty around the benefit provided by other tasks may challenge the generalizability of the trial findings.

Uncertainty in the mental health evidence alongside uncertainty in economic evidence suggests higher levels of uncertainty in the cost-effectiveness evidence as compared to the clinical evidence alone. The cost-effectiveness uncertainty was expressed by the one-way sensitivity analyses (suggesting wide-ranging findings based on PCL-5 instrument improvements and how these improvements are linked to quality-adjusted life years) and by way of the probabilistic sensitivity analyses that suggest SERVs are not highly likely to achieve common thresholds at current pricing. Additional scenario analyses such as the death hazard ratio required to achieve a cost-effectiveness threshold supports further understanding between hypothetical effectiveness (and cost) differences and resulting cost-effectiveness findings. Finally, we note that the potential for bias and corresponding uncertainty in the SERV versus no dog VA payer perspective threshold analyses is greater than that for the SERV vs. EMOT cost-effectiveness analyses. Thus, we did not use any pre-post trial analyses in this threshold analysis. For point of reference, the pre-post change in PCL-5 for SERV (EMOT pre vs. post and post SERV vs. EMOT) was -15.4 units. As a decision aid on the potential value of Veterans with PTSD paired with service dogs, we suggest these threshold findings on PCL-5 or alternatively, VA-12 be used alongside future research that estimates the effectiveness of SERV compared to no dog.

Comprehensive value assessment spans beyond incremental cost-effectiveness findings. We included discussion of potential other benefit and contextual considerations (Section 2.3) to aid in value assessment judgements surrounding SERVs for Veterans with PTSD. Potential other benefits and contextual considerations such as the impact of PTSD on caregivers or on employment or work productivity did not influence the primary analysis incremental cost-effectiveness findings. The SERV intervention's potential impact on Veteran caregivers was not measured within the VA trial. The SERV intervention's potential impact on employment or work productivity was measured but no statistically-significant differences were found. Therefore, the lack of difference in productivity-

related costs led to no changes in the incremental cost-effectiveness findings. However, we provided a societal perspective threshold analysis to show that if confirmed, relatively small increases in average work hours (SERV versus EMOT) that are sustained over time result in cost savings and a favorable cost-effectiveness of SERV versus EMOT. Other unmeasured domains within the societal perspective are not hypothesized to greatly impact the cost-effectiveness of SERV versus EMOT. This is because domains such as patient out of pocket costs and caregiver time costs are likely comparable for those with a service dog versus those with an emotional support dog. If SERV had a larger health impact versus EMOT, we may see spillover effects in terms of cost savings on future unrelated health costs.

The absolute QALY shortfall estimate of 9.02 suggests that compared to the age-matched general US population, Veterans with PTSD suffer from clinical burden like that of treatment resistant major depressive disorder and at higher levels than moderate-to-severe ulcerative colitis or secondary prevention for atherosclerotic cardiovascular disease. Despite this QALY shortfall, given currently available evidence, SERV did not demonstrate substantial QALY gains when compared to EMOT. Further, considerations such as parity in how Veterans with mental health disorders are treated compared to Veterans with physical health disorders did not influence the primary analysis incremental cost-effectiveness findings but may be consistent with the goals of decision makers.

2.4.8 Conclusions

Cost-effectiveness findings may be considered as a starting point for payment-related decision making in heath and should be considered alongside other potential benefits and contextual considerations.[63] We acknowledge lack of high-quality evidence to address the policy-relevant questions comparing SERVs to no dogs for Veterans with PTSD. We provide sensitivity, scenario, and threshold analyses to aid a decision maker's choices around weighting aspects of the evidence. The societal perspective threshold analysis suggests favorable cost-effectiveness findings for SERV if cost savings can be demonstrated by increases in weekly work hours (SERV vs. EMOT). Finally, we provide added contextual considerations and a discussion of other potential benefits and harms to facilitate evidence-based decision making.

Comprehensive Health System Payer Perspective Primary Analysis (including procurement and insurance costs; versus the EMOT intervention)

The primary findings from a comprehensive payer perspective suggest that SERVs paired to Veterans with PTSD have increased costs and small increased health benefits as compared to EMOTs. Given current evidence, incremental findings did not change when taking a broadened societal perspective. At current pricing and based on the $100,000 per QALY threshold, SERV bundled pricing would require reductions of at least 14% (from $42,478 over seven years inclusive

of insurance costs to $36,498 or lower) to promote the efficient allocation of resources belonging to a comprehensive health system payer.

VA Payer Perspective Threshold Analyses (SERV insurance costs only; comparison versus no dog)

Acknowledging additional limitations, the findings of the VA payer perspective threshold scenario suggests that symptom improvement versus usual care without a dog would need to be at least -15.8 units on the PCL-5 total score for the SERV intervention to be cost-effective at $100,000 per QALY gained. Unadjusted pre-post trial analyses that do not permit causal interpretations of the findings yielded -15.4 units on the PCL-5 total score.

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Supplement

1. Full Regression Results (Chapter 1)

Tables 1.A. Effect of a Service Dog on VA costs

Table 1.A.1. Effect of a Service Dog on VA costs: Linear Model with Random Effects

	VA Costs Observation (n) = 1,084; Persons (n) = 181										
Variables	Total	Outpatient Medical/ Surgical	Outpatient Pharmacy	Outpatient Mental health	Outpatient Substance Use	Outpatient Other	Outpatient Total	Inpatient Medical/ Surgical	Inpatient Mental Health	Inpatient Other	Inpatient Total
Service Dog	**663.84**	**-151.98**	**41.27**	**333.66**	**30.34**	**61.50**	**316.09**	**-8.79**	**25.58**	**330.28**	**347.96**
	(784.37)	**(216.63)**	**(135.15)**	**(258.64)**	**(51.67)**	**(139.60)**	**(494.99)**	**(187.36)**	**(157.04)**	**(320.04)**	**(493.21)**
Month 6	-1.81	95.46	48.55	-359.56**	34.97	-50.85	-231.43	323.63	-109.86	15.85	229.62
	(588.98)	(180.43)	(81.01)	(126.26)	(38.97)	(121.75)	(294.00)	(301.54)	(205.73)	(281.12)	(498.29)
Month 9	518.27	254.18	-29.52	-482.70***	71.24	-51.82	-238.62	-96.54	209.99	643.45*	756.89
	(588.98)	(180.43)	(81.01)	(126.26)	(38.97)	(121.75)	(294.00)	(301.54)	(205.73)	(281.12)	(498.29)
Month 12	-265.03	-142.06	-17.04	-539.13***	44.71	55.26	-598.26*	154.98	-202.13	380.38	333.24
	(588.98)	(180.43)	(81.01)	(126.26)	(38.97)	(121.75)	(294.00)	(301.54)	(205.73)	(281.12)	(498.29)
Month 15	112.35	-69.21	134.07	-704.12***	37.76	108.25	-495.15	352.06	-95.50	351.93	607.20
	(589.95)	(180.72)	(81.15)	(126.48)	(39.04)	(121.94)	(294.49)	(301.97)	(206.04)	(281.57)	(499.07)
Month 18	-906.91	-44.30	-50.72	-828.54***	43.25	44.23	-837.97**	-130.06	-90.86	152.97	-69.24
	(589.95)	(180.72)	(81.15)	(126.48)	(39.04)	(121.94)	(294.49)	(301.97)	(206.04)	(281.57)	(499.07)
Male	-1,570.32	-445.45	32.59	-1,280.79***	-1.26	-267.28	-1,962.66**	-115.23	107.44	400.37	392.26
	(982.97)	(271.46)	(169.39)	(324.17)	(64.75)	(174.93)	(620.37)	(234.66)	(196.73)	(401.04)	(618.00)
VA Station 584	967.81	702.08**	-100.12	-423.22	78.38	256.32	511.81	372.42	26.88	57.54	455.74
	(894.04)	(246.92)	(154.05)	(294.79)	(58.89)	(159.12)	(564.19)	(213.59)	(179.02)	(364.80)	(562.20)
VA Station 648	317.23	199.49	142.49	309.96	83.37	-311.61	423.55	278.51	-164.49	-220.27	-106.35
	(1,019.93)	(281.67)	(175.76)	(336.36)	(67.18)	(181.51)	(643.70)	(243.47)	(204.12)	(416.12)	(641.22)
Constant	5,293.41***	1,333.27***	437.96*	2,798.67***	-22.87	943.45***	5,490.82***	79.18	131.18	-407.95	-197.36
	(1,155.23)	(322.99)	(195.12)	(368.87)	(76.13)	(209.44)	(714.15)	(325.11)	(255.54)	(480.64)	(757.51)

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test); standard errors in parentheses

Month 6: 91-180 days post-pairing; Month 9: 181-270 days post-pairing; Month 12: 271-360 days post-pairing; Month 15: 361-450 days post-pairing; Month 18: 451-540 days post-pairing

All costs adjusted to 2018 dollars

Table 1.A.2. Effect of a Service Dog on VA Costs with Time as a Linear Parameter: Linear Model with Random Effects

	VA Costs Observation (n) = 1,084; Persons (n) = 181										
Variables	Total	Outpatient Medical/ Surgical	Outpatient Pharmacy	Outpatient Mental Health	Outpatient Substance Use	Outpatient Other	Outpatient Total	Inpatient Medical/ Surgical	Inpatient Mental Health	Inpatient Other	Inpatient Total
Service Dog	**663.72**	**-152.02**	**41.41**	**333.76**	**30.29**	**61.57**	**316.31**	**-8.68**	**25.58**	**329.82**	**347.65**
	(784.37)	**(216.62)**	**(135.15)**	**(258.64)**	**(51.67)**	**(139.60)**	**(494.99)**	**(187.36)**	**(157.04)**	**(320.04)**	**(493.21)**
Time as a linear effect	-141.98	-31.76	0.42	-149.55***	5.68	23.01	-152.63**	-8.92	-23.53	43.34	10.58
	(99.76)	(30.57)	(13.74)	(21.38)	(6.59)	(20.59)	(49.71)	(51.06)	(34.84)	(47.68)	(84.38)
Male	-1,570.28	-445.43	32.54	-1,280.83***	-1.24	-267.30	-1,962.73**	-115.27	107.43	400.54	392.37
	(982.97)	(271.46)	(169.39)	(324.17)	(64.75)	(174.94)	(620.37)	(234.66)	(196.73)	(401.04)	(618.00)
VA Station 584	967.96	702.14**	-100.30	-423.34	78.44	256.24	511.54	372.28	26.87	58.13	456.12
	(894.04)	(246.92)	(154.05)	(294.79)	(58.89)	(159.12)	(564.19)	(213.59)	(179.02)	(364.80)	(562.20)
VA Station 648	317.24	199.49	142.48	309.95	83.38	-311.62	423.53	278.49	-164.49	-220.22	-106.31
	(1,019.93)	(281.67)	(175.76)	(336.36)	(67.18)	(181.51)	(643.70)	(243.47)	(204.12)	(416.12)	(641.22)
Constant	5,699.83***	1,460.11***	450.67*	2,836.38***	-4.07	880.42***	5,624.74***	211.05	165.48	-302.09	75.31
	(1,145.32)	(319.67)	(194.03)	(367.44)	(75.47)	(207.06)	(710.09)	(315.79)	(250.03)	(475.28)	(746.64)

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test); standard errors in parentheses
All costs adjusted to 2018 dollars

Table 1.A.3. Effect of a Service Dog on VA Costs: GEE Model

	VA Costs Observation (n) = 1,084; Persons (n) = 181										
Variables	Total	Outpatient Medical/ Surgical	Outpatient Pharmacy	Outpatient Mental health	Outpatient Substance Use	Outpatient Other	Outpatient Total	Inpatient Medical/ Surgical	Inpatient Mental Health	Inpatient Other	Inpatient Total
Service Dog	**0.17**	**-0.05**	**0.11**	**0.21**	**2.15****	**0.18**	**0.10**	**did not converge**	**did not converge**	**did not converge**	**1.21***
	(0.16)	**(0.17)**	**(0.24)**	**(0.15)**	**(0.65)**	**(0.17)**	**(0.12)**				**(0.54)**
Month 6	-0.00	0.06	0.13	-0.20*	1.24*	-0.08	-0.06				0.73
	(0.13)	(0.16)	(0.13)	(0.09)	(0.50)	(0.15)	(0.08)				(0.72)
Month 9	0.13	0.15	-0.07	-0.28**	1.77***	-0.19	-0.07				2.95***
	(0.13)	(0.16)	(0.13)	(0.09)	(0.50)	(0.15)	(0.08)				(0.72)
Month 12	-0.07	-0.16	-0.06	-0.35***	0.96	-0.01	-0.16*				1.86**
	(0.13)	(0.16)	(0.13)	(0.09)	(0.50)	(0.15)	(0.08)				(0.72)
Month 15	0.01	-0.07	0.21	-0.44***	0.75	0.06	-0.11				1.05
	(0.13)	(0.16)	(0.13)	(0.09)	(0.50)	(0.15)	(0.08)				(0.72)
Month 18	-0.19	0.02	-0.14	-0.58***	1.14*	0.08	-0.20**				0.41
	(0.13)	(0.16)	(0.13)	(0.09)	(0.50)	(0.15)	(0.08)				(0.72)
Male	-0.31	-0.32	0.08	-0.77***	1.36	-0.25	-0.45**				1.68*
	(0.20)	(0.21)	(0.30)	(0.19)	(0.82)	(0.21)	(0.15)				(0.68)
VA Station 584	0.24	0.56**	-0.23	-0.22	2.99***	0.32	0.16				2.31***
	(0.18)	(0.19)	(0.28)	(0.17)	(0.75)	(0.19)	(0.14)				(0.62)
VA Station 648	0.11	0.22	0.26	0.33	2.20**	-0.49*	0.14				0.81
	(0.21)	(0.22)	(0.32)	(0.20)	(0.85)	(0.22)	(0.16)				(0.71)
Constant	8.51***	7.08***	6.07***	7.94***	-0.98	6.76***	8.58***				1.95*
	(0.24)	(0.25)	(0.35)	(0.22)	(0.96)	(0.25)	(0.18)				(0.89)

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test); standard errors in parentheses

Month 6: 91-180 days post-pairing; Month 9: 181-270 days post-pairing; Month 12: 271-360 days post-pairing; Month 15: 361-450 days post-pairing; Month 18: 451-540 days post-pairing

All costs adjusted to 2018 dollars

Table 1.A.4. Effect of a Service Dog on VA Costs Over Time: Linear Model with Random Effects

	VA Costs over Time Observation (n) = 1,084; Persons (n) = 181										
Variables	Total	Outpatient Medical/ Surgical	Outpatient Pharmacy	Outpatient Mental Health	Outpatient Substance Use	Outpatient Other	Outpatient Total	Inpatient Medical/ Surgical	Inpatient Mental Health	Inpatient Other	Inpatient Total
Service Dog	**1,173.53** **(1,093.97)**	**-178.75** **(318.66)**	**134.41** **(171.12)**	**622.12*** **(305.86)**	**38.22** **(72.18)**	**-76.10** **(210.72)**	**539.85** **(624.39)**	**88.06** **(433.08)**	**395.01** **(308.88)**	**150.64** **(484.90)**	**633.67** **(812.25)**
Month 6	315.75 (865.11)	8.28 (265.11)	91.74 (119.06)	-277.79 (185.23)	22.61 (57.19)	-208.65 (179.06)	-363.80 (431.76)	679.56 (442.91)	-0.00 (301.72)	-0.00 (413.25)	679.56 (732.09)
Month 9	936.50 (865.11)	240.63 (265.11)	-19.14 (119.06)	-277.06 (185.23)	69.05 (57.19)	-139.58 (179.06)	-126.10 (431.76)	-133.94 (442.91)	744.11* (301.72)	452.42 (413.25)	1,062.60 (732.09)
Month 12	-576.81 (865.11)	-157.46 (265.11)	20.77 (119.06)	-405.07* (185.23)	34.69 (57.19)	-6.66 (179.06)	-513.74 (431.76)	-94.45 (442.91)	-0.00 (301.72)	31.38 (413.25)	-63.07 (732.09)
Month 15	482.17 (868.19)	-219.22 (266.05)	256.04* (119.49)	-400.50* (185.91)	20.24 (57.39)	36.86 (179.69)	-310.69 (433.33)	469.21 (444.27)	43.50 (302.70)	282.15 (414.69)	792.18 (734.60)
Month 18	-51.01 (868.19)	136.70 (266.05)	37.26 (119.49)	-622.75*** (185.91)	111.37 (57.39)	-19.13 (179.69)	-360.67 (433.33)	-3.21 (444.27)	111.17 (302.70)	203.70 (414.69)	308.98 (734.60)
Interaction Terms											
Service Dog * Month 6	**-592.57** **(1,181.75)**	**162.67** **(362.15)**	**-80.59** **(162.64)**	**-152.59** **(253.02)**	**23.06** **(78.12)**	**294.45** **(244.60)**	**247.00** **(589.79)**	**-664.16** **(605.02)**	**-204.99** **(412.15)**	**29.58** **(564.50)**	**-839.57** **(1,000.05)**
Service Dog * Month 9	**-780.40** **(1,181.75)**	**25.28** **(362.15)**	**-19.36** **(162.64)**	**-383.72** **(253.02)**	**4.08** **(78.12)**	**163.76** **(244.60)**	**-209.96** **(589.79)**	**69.78** **(605.02)**	**-996.67*** **(412.15)**	**356.45** **(564.50)**	**-570.44** **(1,000.05)**
Service Dog * Month 12	**581.78** **(1,181.75)**	**28.74** **(362.15)**	**-70.55** **(162.64)**	**-250.15** **(253.02)**	**18.69** **(78.12)**	**115.55** **(244.60)**	**-157.71** **(589.79)**	**465.43** **(605.02)**	**-377.17** **(412.15)**	**651.24** **(564.50)**	**739.50** **(1,000.05)**
Service Dog * Month 15	**-687.78** **(1,184.00)**	**278.61** **(362.83)**	**-226.63** **(162.96)**	**-564.56*** **(253.52)**	**32.55** **(78.27)**	**133.27** **(245.06)**	**-342.63** **(590.94)**	**-217.90** **(606.01)**	**-260.02** **(412.87)**	**130.77** **(565.56)**	**-344.48** **(1,001.89)**
Service Dog * Month 18	**-1,589.80** **(1,184.00)**	**-335.62** **(362.83)**	**-163.54** **(162.96)**	**-383.02** **(253.52)**	**-126.36** **(78.27)**	**118.37** **(245.06)**	**-886.06** **(590.94)**	**-235.90** **(606.01)**	**-376.99** **(412.87)**	**-92.85** **(565.56)**	**-703.07** **(1,001.89)**
Male	-1,569.69 (982.95)	-445.39 (271.46)	32.69 (169.39)	-1,280.60*** (324.16)	-1.22 (64.75)	-267.27 (174.93)	-1,962.25** (620.36)	-115.13 (234.66)	107.39 (196.73)	400.53 (401.04)	392.49 (617.99)
VA Station 584	970.03 (894.03)	702.28** (246.92)	-99.75 (154.05)	-422.53 (294.79)	78.52 (58.89)	256.37 (159.12)	513.23 (564.18)	372.78 (213.59)	26.73 (179.02)	58.09 (364.80)	456.53 (562.20)
VA Station 648	317.43 (1,019.91)	199.50 (281.66)	142.53 (175.76)	310.02 (336.36)	83.38 (67.18)	-311.61 (181.51)	423.68 (643.69)	278.54 (243.47)	-164.50 (204.12)	-220.22 (416.12)	-106.28 (641.22)

Constant	5,018.86***	1,347.49***	387.81	2,643.65***	-27.18	1,017.17***	5,370.01***	27.06	-66.70	-312.03	-350.98
	(1,225.56)	(346.50)	(203.10)	(379.11)	(80.79)	(225.96)	(742.77)	(386.77)	(292.60)	(518.92)	(832.95)

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test); standard errors in parentheses

Month 6: 91-180 days post-pairing; Month 9: 181-270 days post-pairing; Month 12: 271-360 days post-pairing; Month 15: 361-450 days post-pairing; Month 18: 451-540 days post-pairing

All costs adjusted to 2018 dollars

Table 1.A.5. Effect of a Service Dog on VA Costs Over Time with Time as a Linear Parameter: Linear Model with Random Effects

	VA Costs over Time Observation (n) = 1,084; Persons (n) = 181										
Variables	Total	Outpatient Medical/ Surgical	Outpatient Pharmacy	Outpatient Mental Health	Outpatient Substance Use	Outpatient Other	Outpatient Total	Inpatient Medical/ Surgical	Inpatient Mental Health	Inpatient Other	Inpatient Total
Service Dog	**1,349.09** **(1,050.78)**	**-19.74** **(304.74)**	**171.62** **(165.93)**	**634.79*** **(298.77)**	**89.06** **(69.31)**	**55.38** **(200.83)**	**929.14** **(605.06)**	**did not converge**	**did not converge**	**did not converge**	**419.62** **(770.38)**
Time as a linear effect	-36.48 (146.75)	-11.40 (44.98)	20.47 (20.21)	-103.20** (31.40)	14.72 (9.70)	22.05 (30.30)	-58.29 (73.04)				21.65 (124.18)
Service Dog * Time as a linear effect	**-196.13** **(200.10)**	**-37.86** **(61.34)**	**-37.27** **(27.55)**	**-86.15*** **(42.81)**	**-16.82** **(13.22)**	**1.77** **(41.31)**	**-175.39** **(99.59)**				**-20.59** **(169.34)**
Male	-1,569.88 (982.96)	-445.35 (271.46)	32.62 (169.39)	-1,280.65*** (324.17)	-1.21 (64.75)	-267.31 (174.94)	-1,962.37** (620.36)				392.41 (618.00)
VA Station 584	969.34 (894.03)	702.41** (246.92)	-100.03 (154.05)	-422.70 (294.79)	78.56 (58.89)	256.23 (159.12)	512.81 (564.18)				456.25 (562.20)
VA Station 648	317.37 (1,019.92)	199.52 (281.66)	142.50 (175.76)	310.00 (336.36)	83.39 (67.18)	-311.62 (181.51)	423.64 (643.69)				-106.30 (641.22)
Constant	5,330.85*** (1,205.59)	1,388.90*** (339.86)	380.56 (200.83)	2,674.29*** (376.14)	-35.71 (79.46)	883.75*** (221.18)	5,294.77*** (734.33)				36.57 (811.80)

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test); standard errors in parentheses
All costs adjusted to 2018 dollars

Table 1.A.6. Effect of a Service Dog on VA Costs Over Time: Linear Model with Fixed Effects

	VA Costs over Time Observation (n) = 1,084; Persons (n) = 181										
Variables	Total	Outpatient Medical/ Surgical	Outpatient Pharmacy	Outpatient Mental Health	Outpatient Substance Use	Outpatient Other	Outpatient Total	Inpatient Medical/ Surgical	Inpatient Mental Health	Inpatient Other	Inpatient Total
Month 6	315.75 (865.32)	8.28 (265.11)	91.74 (119.11)	-277.79 (185.31)	22.61 (57.21)	-208.65 (179.08)	-363.80 (431.85)	did not converge	did not converge	did not converge	679.56 (732.36)
Month 9	936.50 (865.32)	240.63 (265.11)	-19.14 (119.11)	-277.06 (185.31)	69.05 (57.21)	-139.58 (179.08)	-126.10 (431.85)				1,062.60 (732.36)
Month 12	-576.81 (865.32)	-157.46 (265.11)	20.77 (119.11)	-405.07* (185.31)	34.69 (57.21)	-6.66 (179.08)	-513.74 (431.85)				-63.07 (732.36)
Month 15	471.69 (868.58)	-224.73 (266.11)	256.43* (119.56)	-400.89* (186.00)	19.98 (57.42)	33.62 (179.75)	-315.59 (433.47)				787.28 (735.11)
Month 18	-61.48 (868.58)	131.19 (266.11)	37.64 (119.56)	-623.14*** (186.00)	111.11 (57.42)	-22.37 (179.75)	-365.57 (433.47)				304.08 (735.11)
Interaction Terms											
Service Dog * Month 6	**-592.57** **(1,182.04)**	**162.67** **(362.14)**	**-80.59** **(162.71)**	**-152.59** **(253.13)**	**23.06** **(78.15)**	**294.45** **(244.63)**	**247.00** **(589.91)**				**-839.57** **(1,000.41)**
Service Dog * Month 9	**-780.40** **(1,182.04)**	**25.28** **(362.14)**	**-19.36** **(162.71)**	**-383.72** **(253.13)**	**4.08** **(78.15)**	**163.76** **(244.63)**	**-209.96** **(589.91)**				**-570.44** **(1,000.41)**
Service Dog * Month 12	**581.78** **(1,182.04)**	**28.74** **(362.14)**	**-70.55** **(162.71)**	**-250.15** **(253.13)**	**18.69** **(78.15)**	**115.55** **(244.63)**	**-157.71** **(589.91)**				**739.50** **(1,000.41)**
Service Dog * Month 15	**-677.31** **(1,184.42)**	**284.13** **(362.87)**	**-227.01** **(163.04)**	**-564.17*** **(253.64)**	**32.81** **(78.31)**	**136.50** **(245.12)**	**-337.74** **(591.10)**				**-339.57** **(1,002.42)**
Service Dog * Month 18	**-1,579.33** **(1,184.42)**	**-330.10** **(362.87)**	**-163.93** **(163.04)**	**-382.63** **(253.64)**	**-126.10** **(78.31)**	**121.61** **(245.12)**	**-881.16** **(591.10)**				**-698.16** **(1,002.42)**
Constant	4,842.37*** (416.87)	1,211.96*** (127.72)	481.82*** (57.38)	1,865.95*** (89.27)	42.20 (27.56)	787.01*** (86.27)	4,388.94*** (208.04)				453.43 (352.81)
R-Squared	0.01	0.01	0.01	0.06	0.01	0.00	0.02				0.01

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test); standard errors in parentheses

Month 6: 91-180 days post-pairing; Month 9: 181-270 days post-pairing; Month 12: 271-360 days post-pairing; Month 15: 361-450 days post-pairing; Month 18: 451-540 days post-pairing. All costs adjusted to 2018 dollars

Table 1.A.7. Effect of a Service Dog on VA Costs Over Time: GEE model

	VA Costs over Time Observation (n) = 1,084; Persons (n) = 181										
Variables	Total	Outpatient Medical/ Surgical	Outpatient Pharmacy	Outpatient Mental Health	Outpatient Substance Use	Outpatient Other	Outpatient Total	Inpatient Medical/ Surgical	Inpatient Mental Health	Inpatient Other	Inpatient Total
Service Dog	**0.28** **(0.23)**	**-0.08** **(0.25)**	**0.27** **(0.29)**	**0.33** **(0.19)**	**2.21**** **(0.84)**	**-0.09** **(0.25)**	**0.16** **(0.16)**	**did not converge**	**did not converge**	**did not converge**	**did not converge**
Month 6	0.05 (0.18)	-0.07 (0.22)	0.22 (0.19)	-0.18 (0.14)	0.59 (0.64)	-0.41 (0.22)	-0.10 (0.11)				
Month 9	0.23 (0.18)	0.12 (0.22)	-0.06 (0.19)	-0.18 (0.14)	2.10*** (0.64)	-0.32 (0.22)	-0.04 (0.11)				
Month 12	-0.16 (0.18)	-0.13 (0.22)	0.03 (0.19)	-0.32* (0.14)	0.97 (0.64)	-0.12 (0.22)	-0.15 (0.11)				
Month 15	0.11 (0.18)	-0.19 (0.22)	0.39* (0.19)	-0.28* (0.14)	0.42 (0.64)	-0.02 (0.22)	-0.07 (0.11)				
Month 18	-0.01 (0.18)	0.16 (0.22)	0.04 (0.19)	-0.47*** (0.14)	1.47* (0.64)	-0.13 (0.22)	-0.08 (0.11)				
Interaction Terms											
Service Dog * Month 6	**-0.10** **(0.25)**	**0.22** **(0.30)**	**-0.17** **(0.26)**	**-0.03** **(0.19)**	**1.01** **(0.87)**	**0.59*** **(0.30)**	**0.07** **(0.15)**				
Service Dog * Month 9	**-0.20** **(0.25)**	**0.07** **(0.30)**	**-0.01** **(0.26)**	**-0.18** **(0.19)**	**-0.64** **(0.87)**	**0.24** **(0.30)**	**-0.06** **(0.15)**				
Service Dog * Month 12	**0.16** **(0.25)**	**-0.06** **(0.30)**	**-0.16** **(0.26)**	**-0.04** **(0.19)**	**0.02** **(0.87)**	**0.21** **(0.30)**	**-0.02** **(0.15)**				
Service Dog * Month 15	**-0.18** **(0.25)**	**0.22** **(0.30)**	**-0.34** **(0.26)**	**-0.31** **(0.19)**	**0.56** **(0.87)**	**0.17** **(0.30)**	**-0.08** **(0.15)**				
Service Dog * Month 18	**-0.34** **(0.25)**	**-0.27** **(0.30)**	**-0.34** **(0.26)**	**-0.20** **(0.19)**	**-0.75** **(0.87)**	**0.40** **(0.30)**	**-0.23** **(0.15)**				
Male	-0.32 (0.20)	-0.32 (0.20)	0.08 (0.30)	-0.77*** (0.19)	1.28 (0.79)	-0.26 (0.21)	-0.45** (0.15)				
VA Station 584	0.24 (0.18)	0.57** (0.19)	-0.23 (0.27)	-0.23 (0.18)	3.13*** (0.71)	0.33 (0.19)	0.16 (0.14)				
VA Station 648	0.11 (0.21)	0.22 (0.21)	0.24 (0.31)	0.34 (0.20)	2.21** (0.82)	-0.51* (0.22)	0.15 (0.16)				
Constant	8.45*** (0.25)	7.10*** (0.27)	5.99*** (0.36)	7.87*** (0.23)	-1.02 (0.96)	6.91*** (0.27)	8.55*** (0.18)				

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test). standard errors in parentheses

Month 6: 91-180 days post-pairing; Month 9: 181-270 days post-pairing; Month 12: 271-360 days post-pairing; Month 15: 361-450 days post-pairing; Month 18: 451-540 days post-pairing. All costs adjusted to 2018 dollars.

Tables 1.B. Effect of a Service Dog on VA Utilization

Table 1.B.1. Effect of a Service Dog on VA Utilization: Negative Binomial Regression

	VA Utilization Observations (n) = 1,084; Persons (n) = 181							
Variables	Outpatient Medical/ Surgical	Outpatient Pharmacy	Outpatient Mental Health	Outpatient Substance Use	Outpatient Other	Outpatient Days	Inpatient Length of Stay	Inpatient Admissions
Service Dog	**-0.09**	**-0.08**	**0.04**	**1.12***	**0.02**	**0.03**	**0.82**	**0.35**
	(0.13)	**(0.13)**	**(0.13)**	**(0.56)**	**(0.13)**	**(0.10)**	**(0.49)**	**(0.53)**
Month 6	-0.05	0.06	-0.14*	-0.06	0.03	-0.02	-0.09	-0.13
	(0.08)	(0.04)	(0.06)	(0.35)	(0.09)	(0.04)	(0.58)	(0.55)
Month 9	0.01	0.00	-0.29***	0.35	0.05	-0.06	-0.02	-0.06
	(0.07)	(0.04)	(0.06)	(0.33)	(0.09)	(0.04)	(0.58)	(0.55)
Month 12	-0.14	-0.01	-0.38***	-0.07	0.00	-0.12***	0.12	-0.62
	(0.08)	(0.04)	(0.06)	(0.35)	(0.09)	(0.04)	(0.55)	(0.63)
Month 15	-0.02	-0.00	-0.40***	0.15	0.14	-0.09*	0.36	0.37
	(0.08)	(0.04)	(0.06)	(0.34)	(0.09)	(0.04)	(0.54)	(0.49)
Month 18	-0.01	-0.04	-0.43***	0.03	0.13	-0.10**	0.19	-0.29
	(0.08)	(0.04)	(0.16)	(0.36)	(0.09)	(0.04)	(0.55)	(0.58)
Male	-0.23	-0.01	-0.43**	0.15	-0.17	-0.20	1.00	0.44
	(0.16)	(0.16)	(0.16)	(0.69)	(0.16)	(0.13)	(0.64)	(0.69)
VA Station 584	0.47**	0.03	-0.18	1.49*	0.00	0.02	0.78	1.22*
	(0.14)	(0.15)	(0.14)	(0.66)	(0.14)	(0.11)	(0.56)	(0.62)
VA Station 648	-0.08	0.08	0.23	0.31	-0.40*	-0.04	0.35	0.57
	(0.17)	(0.17)	(0.16)	(0.70)	(0.17)	(0.13)	(0.68)	(0.72)
Constant	2.01***	1.90***	2.70***	-1.79	1.44***	3.41***	-4.36***	-1.07
	(0.24)	(0.19)	(0.22)	(1.00)	(0.20)	(0.19)	(0.87)	(1.30)

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test); standard errors in parentheses
Month 6: 91-180 days post-pairing; Month 9: 181-270 days post-pairing; Month 12: 271-360 days post-pairing; Month 15: 361-450 days post-pairing; Month 18: 451-540 days post-pairing

Table 1.B.2. Effect of a Service Dog on VA Utilization: Linear model with Random Effects

	VA Utilization Observation (n) = 1,084; Persons (n) = 181							
Variables	Outpatient Medical/ Surgical	Outpatient Pharmacy	Outpatient Mental Health	Outpatient Substance Use	Outpatient Other	Outpatient Days	Inpatient Length of Stay	Inpatient Admissions
Service Dog	**-0.66**	**-0.49**	**0.89**	**0.04**	**-0.21**	**-0.40**	**0.44**	**0.01**
	(0.44)	**(0.81)**	**(0.73)**	**(0.21)**	**(0.54)**	**(1.34)**	**(0.60)**	**(0.02)**
Month 6	-0.22	0.40	-0.76*	0.04	-0.12	-0.35	-0.08	-0.01
	(0.24)	(0.26)	(0.33)	(0.16)	(0.32)	(0.52)	(0.46)	(0.02)
Month 9	-0.01	0.03	-1.28***	0.29	0.28	-0.64	0.92*	0.01
	(0.24)	(0.26)	(0.33)	(0.16)	(0.32)	(0.52)	(0.46)	(0.02)
Month 12	-0.52*	-0.07	-1.75***	0.05	-0.04	-1.71***	0.31	-0.02
	(0.24)	(0.26)	(0.33)	(0.16)	(0.32)	(0.52)	(0.46)	(0.02)
Month 15	-0.16	0.00	-1.88***	0.11	0.44	-1.18*	0.72	0.02
	(0.24)	(0.26)	(0.33)	(0.16)	(0.32)	(0.52)	(0.46)	(0.02)
Month 18	-0.09	-0.25	-1.89***	0.22	0.44	-1.27*	0.50	-0.01
	(0.24)	(0.26)	(0.33)	(0.16)	(0.32)	(0.52)	(0.46)	(0.02)
Male	-1.16*	-0.06	-1.98*	-0.01	-0.40	-2.76	0.59	0.01
	(0.55)	(1.01)	(0.91)	(0.27)	(0.67)	(1.68)	(0.76)	(0.03)
VA Station 584	1.40**	0.22	-1.44	0.46	0.94	0.71	0.65	0.04
	(0.50)	(0.92)	(0.83)	(0.24)	(0.61)	(1.53)	(0.69)	(0.02)
VA Station 648	-0.54	0.48	-0.20	0.37	-0.93	-0.54	-0.27	0.01
	(0.57)	(1.05)	(0.94)	(0.28)	(0.70)	(1.74)	(0.79)	(0.03)
Constant	4.15***	6.72***	7.42***	-0.06	3.32***	17.40***	-0.56	0.01
	(0.63)	(1.14)	(1.03)	(0.32)	(0.77)	(1.89)	(0.89)	(0.03)

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test); standard errors in parentheses

Month 6: 91-180 days post-pairing; Month 9: 181-270 days post-pairing; Month 12: 271-360 days post-pairing; Month 15: 361-450 days post-pairing; Month 18: 451-540 days post-pairing

Table 1.B.3. Effect of a Service Dog on VA Utilization with Time as a Linear Parameter: Linear model with Random Effects

	VA Utilization Observation (n) = 1,084; Persons (n) = 181							
Variables	Outpatient Medical/ Surgical	Outpatient Pharmacy	Outpatient mental Health	Outpatient Substance Use	Outpatient Other	Outpatient Days	Inpatient Length of Stay	Inpatient Admissions
Service Dog	**-0.66**	**-0.49**	**0.89**	**0.04**	**-0.21**	**-0.39**	**0.44**	**0.01**
	(0.44)	**(0.81)**	**(0.73)**	**(0.21)**	**(0.54)**	**(1.34)**	**(0.60)**	**(0.02)**
Time as a linear effect	-0.02	-0.07	-0.38***	0.03	0.10	-0.28**	0.12	0.00
	(0.04)	(0.04)	(0.06)	(0.03)	(0.05)	(0.09)	(0.08)	(0.00)
Male	-1.17*	-0.06	-1.99*	-0.01	-0.40	-2.76	0.59	0.01
	(0.55)	(1.01)	(0.91)	(0.27)	(0.67)	(1.68)	(0.76)	(0.03)
VA Station 584	1.40**	0.22	-1.44	0.46	0.93	0.71	0.65	0.04
	(0.50)	(0.92)	(0.83)	(0.24)	(0.61)	(1.53)	(0.69)	(0.02)
VA Station 648	-0.54	0.48	-0.20	0.37	-0.93	-0.54	-0.27	0.01
	(0.57)	(1.05)	(0.94)	(0.28)	(0.70)	(1.74)	(0.79)	(0.03)
Constant	4.06***	6.99***	7.49***	-0.05	3.14***	17.53***	-0.59	0.01
	(0.63)	(1.14)	(1.03)	(0.31)	(0.77)	(1.89)	(0.88)	(0.03)

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test); standard errors in parentheses

Month 6: 91-180 days post-pairing; Month 9: 181-270 days post-pairing; Month 12: 271-360 days post-pairing; Month 15: 361-450 days post-pairing; Month 18: 451-540 days post-pairing

Table 1.B.4. Effect of a Service Dog on VA Utilization Over Time: Negative Binomial Regression

	VA Utilization Over Time Observation (n) = 1,084; Persons (n) = 181							
Variables	Outpatient Medical/ Surgical	Outpatient Pharmacy	Outpatient Mental Health	Outpatient Substance Use	Outpatient Other	Outpatient Days	Inpatient Length of Stay	Inpatient Admissions
Service Dog	**-0.22** **(0.16)**	**-0.06** **(0.14)**	**0.09** **(0.15)**	**1.57*** **(0.73)**	**-0.04** **(0.17)**	**0.03** **(0.11)**	**2.36*** **(1.16)**	**1.84** **(1.15)**
Month 6	-0.13 (0.11)	0.06 (0.06)	-0.23* (0.09)	0.34 (0.56)	-0.07 (0.13)	-0.05 (0.05)	1.16 (1.15)	1.10 (1.15)
Month 9	-0.06 (0.10)	0.00 (0.06)	-0.23* (0.09)	0.68 (0.55)	0.01 (0.12)	-0.05 (0.05)	1.25 (1.15)	1.23 (1.15)
Month 12	-0.23* (0.11)	-0.01 (0.06)	-0.37*** (0.10)	0.13 (0.59)	-0.09 (0.13)	-0.13* (0.05)	0.70 (1.22)	0.00 (1.41)
Month 15	-0.11 (0.10)	0.03 (0.06)	-0.30** (0.10)	0.29 (0.58)	0.07 (0.12)	-0.07 (0.05)	1.62 (1.12)	1.57 (1.10)
Month 18	-0.06 (0.10)	-0.01 (0.06)	-0.30** (0.10)	0.82 (0.56)	0.22 (0.12)	-0.05 (0.05)	1.61 (1.12)	1.33 (1.13)
Interaction Terms								
Service Dog * Month 6	**0.16** **(0.15)**	**-0.00** **(0.08)**	**0.15** **(0.12)**	**-0.63** **(0.72)**	**0.19** **(0.17)**	**0.06** **(0.07)**	**-1.88** **(1.36)**	**-1.72** **(1.34)**
Service Dog * Month 9	**0.13** **(0.15)**	**0.00** **(0.08)**	**-0.10** **(0.13)**	**-0.49** **(0.69)**	**0.07** **(0.18)**	**-0.02** **(0.07)**	**-1.91** **(1.36)**	**-1.82** **(1.34)**
Service Dog * Month 12	**0.20** **(0.15)**	**-0.01** **(0.08)**	**-0.02** **(0.13)**	**-0.32** **(0.73)**	**0.17** **(0.18)**	**0.01** **(0.07)**	**-0.77** **(1.37)**	**-0.79** **(1.58)**
Service Dog * Month 15	**0.17** **(0.15)**	**-0.05** **(0.08)**	**-0.18** **(0.13)**	**-0.22** **(0.71)**	**0.14** **(0.17)**	**-0.04** **(0.07)**	**-1.87** **(1.30)**	**-1.66** **(1.25)**
Service Dog * Month 18	**0.12** **(0.15)**	**-0.05** **(0.08)**	**-0.22** **(0.13)**	**-1.22** **(0.72)**	**-0.18** **(0.17)**	**-0.10** **(0.07)**	**-2.22** **(1.33)**	**-2.53** **(1.40)**
Male	-0.24 (0.16)	-0.01 (0.16)	-0.45** (0.16)	0.20 (0.71)	-0.16 (0.16)	-0.20 (0.13)	1.06 (0.64)	0.46 (0.70)
VA Station 584	0.47** (0.14)	0.03 (0.15)	-0.18 (0.15)	1.62* (0.67)	-0.01 (0.15)	0.02 (0.11)	0.81 (0.56)	1.25* (0.62)
VA Station 648	-0.08 (0.17)	0.07 (0.17)	0.20 (0.16)	0.33 (0.71)	-0.42* (0.17)	-0.05 (0.13)	0.30 (0.68)	0.56 (0.72)
Constant	2.09***	1.89***	2.73***	-2.11	1.49***	3.43***	-5.46***	-2.05

	(0.25)	(0.19)	(0.23)	(1.09)	(0.21)	(0.19)	(1.26)	(1.64)

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test); standard errors in parentheses
Month 6: 91-180 days post-pairing; Month 9: 181-270 days post-pairing; Month 12: 271-360 days post-pairing; Month 15: 361-450 days post-pairing; Month 18: 451-540 days post-pairing

Table 1.B.5. Effect of a Service Dog on VA Utilization Over Time: Linear Model with Random Effects

	VA Utilization Over Time Observation (n) = 1,084; Persons (n) = 181							
Variables	Outpatient Medical/ Surgical	Outpatient Pharmacy	Outpatient mental health	Outpatient Substance Use	Outpatient Other	Outpatient Days	Inpatient Length of Stay	Inpatient Admissions
Service Dog	**-1.09***	**-0.37**	**1.59**	**0.15**	**0.01**	**-0.10**	**0.63**	**0.06**
	(0.54)	**(0.88)**	**(0.84)**	**(0.30)**	**(0.68)**	**(1.50)**	**(0.85)**	**(0.04)**
Month 6	-0.48	0.43	-0.86	0.06	-0.21	-0.65	0.08	0.02
	(0.35)	(0.39)	(0.48)	(0.24)	(0.47)	(0.76)	(0.67)	(0.04)
Month 9	-0.26	0.01	-0.77	0.26	0.51	-0.50	1.27	0.04
	(0.35)	(0.39)	(0.48)	(0.24)	(0.47)	(0.76)	(0.67)	(0.04)
Month 12	-0.83*	-0.05	-1.42**	0.11	-0.13	-1.73*	0.06	0.00
	(0.35)	(0.39)	(0.48)	(0.24)	(0.47)	(0.76)	(0.67)	(0.04)
Month 15	-0.52	0.18	-1.24*	0.10	0.44	-0.99	0.90	0.05
	(0.35)	(0.39)	(0.48)	(0.24)	(0.47)	(0.76)	(0.67)	(0.04)
Month 18	-0.28	-0.08	-1.01*	0.55*	1.11*	-0.31	0.66	0.04
	(0.35)	(0.39)	(0.48)	(0.24)	(0.47)	(0.76)	(0.67)	(0.04)
Interaction Terms								
Service Dog * Month 6	**0.49**	**-0.05**	**0.18**	**-0.04**	**0.17**	**0.57**	**-0.31**	**-0.05**
	(0.47)	**(0.53)**	**(0.66)**	**(0.32)**	**(0.64)**	**(1.04)**	**(0.91)**	**(0.05)**
Service Dog * Month 9	**0.47**	**0.03**	**-0.95**	**0.06**	**-0.43**	**-0.26**	**-0.66**	**-0.06**
	(0.47)	**(0.53)**	**(0.66)**	**(0.32)**	**(0.64)**	**(1.04)**	**(0.91)**	**(0.05)**
Service Dog * Month 12	**0.59**	**-0.05**	**-0.62**	**-0.11**	**0.17**	**0.03**	**0.48**	**-0.04**
	(0.47)	**(0.53)**	**(0.66)**	**(0.32)**	**(0.64)**	**(1.04)**	**(0.91)**	**(0.05)**
Service Dog * Month 15	**0.66**	**-0.34**	**-1.20**	**0.02**	**-0.01**	**-0.36**	**-0.35**	**-0.05**
	(0.47)	**(0.53)**	**(0.66)**	**(0.32)**	**(0.64)**	**(1.04)**	**(0.92)**	**(0.05)**
Service Dog * Month 18	**0.36**	**-0.31**	**-1.63***	**-0.63**	**-1.26***	**-1.77**	**-0.30**	**-0.09**
	(0.47)	**(0.53)**	**(0.66)**	**(0.32)**	**(0.64)**	**(1.04)**	**(0.92)**	**(0.05)**
Male	-1.16*	-0.06	-1.98*	-0.01	-0.40	-2.76	0.59	0.01
	(0.55)	(1.01)	(0.91)	(0.27)	(0.67)	(1.68)	(0.76)	(0.03)
VA Station 584	1.40**	0.23	-1.44	0.47	0.94	0.72	0.65	0.04
	(0.50)	(0.92)	(0.83)	(0.24)	(0.61)	(1.53)	(0.69)	(0.02)
VA Station 648	-0.54	0.48	-0.20	0.37	-0.93	-0.54	-0.27	0.01
	(0.57)	(1.05)	(0.94)	(0.28)	(0.70)	(1.74)	(0.79)	(0.03)
Constant	4.38***	6.65***	7.04***	-0.12	3.20***	17.23***	-0.66	-0.01

	(0.65)	(1.15)	(1.06)	(0.34)	(0.80)	(1.93)	(0.95)	(0.04)

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test); standard errors in parentheses
Month 6: 91-180 days post-pairing; Month 9: 181-270 days post-pairing; Month 12: 271-360 days post-pairing; Month 15: 361-450 days post-pairing; Month 18: 451-540 days post-pairing

Table 1.B.6. Effect of a Service Dog on VA Utilization Over Time with Time as a Linear Parameter: Linear Model with Random Effects

	VA Utilization Over Time Observation (n) = 1,084; Persons (n) = 181							
Variables	Outpatient Medical/ Surgical	Outpatient Pharmacy	Outpatient mental health	Outpatient Substance Use	Outpatient Other	Outpatient Days	Inpatient Length of Stay	Inpatient Admissions
Service Dog	**-0.91**	**-0.24**	**2.08***	**0.35**	**0.41**	**0.74**	**0.49**	**0.05**
	(0.52)	**(0.87)**	**(0.82)**	**(0.29)**	**(0.66)**	**(1.48)**	**(0.81)**	**(0.04)**
Time as a linear effect	-0.06	-0.03	-0.20*	0.08	0.20*	-0.11	0.13	0.01
	(0.06)	(0.07)	(0.08)	(0.04)	(0.08)	(0.13)	(0.11)	(0.01)
Service Dog * Time as a linear effect	**0.07**	**-0.07**	**-0.34****	**-0.09**	**-0.18**	**-0.32**	**-0.01**	**-0.01**
	(0.08)	**(0.09)**	**(0.11)**	**(0.05)**	**(0.11)**	**(0.18)**	**(0.15)**	**(0.01)**
Male	-1.17*	-0.06	-1.98*	-0.01	-0.40	-2.76	0.59	0.01
	(0.55)	(1.01)	(0.91)	(0.27)	(0.67)	(1.68)	(0.76)	(0.03)
VA Station 584	1.40**	0.23	-1.44	0.47	0.94	0.72	0.65	0.04
	(0.50)	(0.92)	(0.83)	(0.24)	(0.61)	(1.53)	(0.69)	(0.02)
VA Station 648	-0.54	0.48	-0.20	0.37	-0.93	-0.54	-0.27	0.01
	(0.57)	(1.05)	(0.94)	(0.28)	(0.70)	(1.74)	(0.79)	(0.03)
Constant	4.19***	6.86***	6.85***	-0.21	2.80***	16.92***	-0.62	-0.01
	(0.65)	(1.15)	(1.05)	(0.33)	(0.79)	(1.92)	(0.93)	(0.04)

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test); standard errors in parentheses

Tables 1.C. Effect of a Service Dog on Non-VA Utilization

Table 1.C.1. Effect of a Service Dog on Non-VA Utilization: Complete Case Analysis

	Beta Coefficient		
Variables	Non-VA Clinic visits	Non-VA Hospitalization	Non-VA ER Visits
Service dog	**-0.19** **(-0.68, 0.29)**	**0.38** **(-0.49, 1.26)**	**-0.16** **(-0.92, 0.60)**
Month 6	0.02 (-0.38, 0.43)	-0.13 (-1.22, 0.96)	-0.26 (-1.29, 0.77)
Month 9	0.04 (-0.37, 0.44)	0.31 (-0.68, 1.30)	0.62 (-0.24, 1.48)
Month 12	-0.10 (-0.52, 0.32)	-0.25 (-1.40, 0.90)	0.55 (-0.30, 1.41)
Month 15	0.05 (-0.37, 0.47)	-1.83 (-3.92, 0.27)	0.05 (-0.92, 1.02)
Month 18	-0.06 (-0.49, 0.36)	-1.13 (-2.70, 0.45)	0.33 (-0.57, 1.22)
Baseline value of outcome	0.18*** (0.08, 0.27)	0.49 (-1.33, 2.30)	1.25* (0.23, 2.26)
Constant	-0.82*** (-1.31, -0.34)	-3.44*** (-4.38, -2.50)	0.09 (-1.95, 2.13)
Observations (n)	961	955	954
Persons (n)	170	170	169

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test); 95% Confidence Intervals in parentheses

Table 1.C.2. Effect of a Service Dog on Non-VA Utilization Over Time: Complete Case Analysis

	Beta Coefficient		
Variables	Non-VA Clinic visits	Non-VA Hospitalization	Non-VA ER Visits
Service Dog	**0.06** **(-0.65, 0.77)**	**0.76** **(-1.09, 2.61)**	**-0.27** **(-1.68, 1.14)**
Month 6	0.15 (-0.44, 0.74)	0.89 (-0.94, 2.72)	-0.25 (-1.68, 1.17)
Month 9	0.18 (-0.41, 0.77)	0.17 (-1.92, 2.25)	0.07 (-1.35, 1.50)
Month 12	0.02 (-0.59, 0.62)	0.21 (-1.88, 2.29)	0.51 (-0.68, 1.69)
Month 15	0.36 (-0.23, 0.95)	-1.68 (-3.92, 0.55)	0.30 (-0.94, 1.54)
Month 18	0.07 (-0.55, 0.69)	-0.94 (-2.69, 0.81)	0.21 (-1.05, 1.46)
Interaction terms			
Service Dog * Month 6	**-0.24** **(-1.05, 0.57)**	**-1.93** **(-4.46, 0.60)**	**-0.03** **(-2.09, 2.04)**
Service Dog * Month 9	**-0.27** **(-1.08, 0.54)**	**0.28** **(-2.16, 2.72)**	**0.8525** **(-0.99, 2.69)**
Service Dog * Month 12	**-0.23** **(-1.07, 0.61)**	**-0.74** **(-3.34, 1.86)**	**0.07** **(-1.64, 1.79)**
Service Dog * Month 15	**-0.61** **(-1.45, 0.23)**	**--**	**-0.67** **(-2.70, 1.36)**
Service Dog * Month 18	**-0.26** **(-1.12, 0.59)**	**--**	**0.24** **(-1.56, 2.03)**
Baseline value of outcome	0.18*** (0.08, 0.28)	0.73 (-1.39, 2.86)	1.25* (0.25, 2.24)
Constant	-0.95** (-1.52, -0.38)	-4.49*** (-6.29, -2.68)	-0.14 (-1.86, 1.59)
Observations (n) Persons (n)	961 170	825 170	954 169

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test); 95% Confidence Intervals in parentheses

Table 1.C.3. Effect of a Service Dog on Non-VA Utilization: Multiple Imputation Analysis

	Beta Coefficient		
Variables	Non-VA Clinic visits	Non-VA Hospitalization	Non-VA ER Visits
Service Dog	**-0.42** **(-0.88, 0.03)**	**0.48** **(-0.49, 1.46)**	**-0.29** **(-0.97, 0.38)**
Month 6	0.05 (-0.35, 0.45)	-0.16 (-1.32, 1.01)	-0.29 (-1.33, 0.75)
Month 9	0.08 (-0.35, 0.51)	0.35 (-0.72, 1.43)	0.77 (-0.05, 1.59)
Month 12	0.03 (-0.39, 0.45)	-0.34 (-1.56, 0.88)	0.67 (-0.16, 1.50)
Month 15	0.17 (-0.24, 0.57)	-2.08 (-4.23, 0.06)	0.22 (-0.69, 1.14)
Month 18	0.08 (-0.33, 0.50)	-1.37 (-2.99, 0.27)	0.33 (-0.53, 1.20)
Baseline value of outcome	0.12* (0.01, 0.23)	0.73 (-1.32, 2.79)	1.17* (0.28, 2.07)
Constant	-0.59* (-1.08, -0.10)	-4.29*** (-5.60, -2.98)	0.57 (-2.19 3.32)
Observations (n)	1,086	1,086	1,086
Persons (n)	181	181	181

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test); 95% Confidence Intervals in parentheses

Table 1.C.4. Effect of a Service Dog on Non-VA Utilization Over Time: Multiple Imputation Analysis

	Beta Coefficient		
	Non-VA Clinic visits	Non-VA Hospitalization	Non-VA ER Visits
Service Dog	**-0.16** **(-0.88, 0.56)**	**0.81** **(-1.02, 2.64)**	**-0.32** **(-1.71, 1.06)**
Month 6	0.19 (-0.36, 0.73)	0.81 (-0.99, 2.62)	-0.33 (-1.76, 1.10)
Month 9	0.24 (-0.37, 0.86)	0.22 (-1.86, 2.29)	0.51 (-0.73, 1.75)
Month 12	0.15 (-0.46, 0.77)	0.05 (-2.01, 2.11)	0.64 (-0.54, 1.81)
Month 15	0.40 (-0.16, 0.96)	-1.77 (-4.00, 0.45)	0.43 (-0.74, 1.60)
Month 18	0.15 (-0.44, 0.75)	-1.04 (-2.77, 0.70)	0.28 (-0.90, 1.46)
Interaction Terms			
Service Dog * Month 6	**-0.31** **(-1.09, 0.48)**	**-1.85** **(-4.36, 0.66)**	**0.07** **(-1.98, 2.13)**
Service Dog * Month 9	**-0.37** **(-1.22, 0.48)**	**0.19** **(-2.23, 2.62)**	**0.46** **(-1.24, 2.17)**
Service Dog * Month 12	**-0.26** **(-1.11, 0.59)**	**-0.60** **(-3.18, 1.97)**	**0.04** **(-1.71, 1.79)**
Service Dog * Month 15	**-0.52** **(-1.31, 0.26)**	**0.00** **(0.00, 0.00)**	**-0.63** **(-2.59, 1.33)**
Service Dog * Month 18	**-0.14** **(-0.98, 0.70)**	**0.00** **(0.00, 0.00)**	**0.11** **(-1.64, 1.85)**
Baseline value of outcome	0.12* (0.00, 0.23)	0.75 (-1.34, 2.84)	1.18** (0.29, 2.08)
Constant	-0.70* (-1.27, -0.12)	-4.56*** (-6.31, -2.81)	0.29 (-1.91, 2.49)
Observations (n)	1,086	918	1,086

Persons (n)	181	181	181

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test); 95% Confidence Intervals in parentheses

Tables 1.D. Employment and Labor Market Outcomes

Table 1.D.1. Employment and Labor Market Outcomes: Complete Case

	Employment and Labor Market Outcomes						
Variables	Employed	Missed work due to health	Missed work other reasons	Actual hours worked	Impact of Health on Work Productivity (0-10)^	Impact of Health on Regular Activities (0-10)^	Impact of Health on Overall Productivity^
Service Dog	**0.64**	**-1.80**	**-1.24**	**5.30**	**-0.06**	**-0.36**	**-0.24**
	(-0.79, 2.07)	**(-5.0, 1.4)**	**(-3.79, 1.31)**	**(-1.13, 11.72)**	**(-1.51, 1.38)**	**(-0.97, 0.25)**	**(-0.86, 0.38)**
Month 6	-0.15	0.37	-0.27	2.09	-0.358	-0.274	-0.230
	(-1.16, 0.86)	(-2.73, 3.47)	(-3.09, 2.55)	(-2.61, 6.80)	(-1.18, 0.46)	(-0.67, 0.12)	(-0.64, 0.18)
Month 9	-0.34	0.18	-1.24	1.79	-0.64	0.02	-0.13
	(-1.38, 0.69)	(-3.03, 3.38)	(-4.15, 1.67)	(-3.12, 6.70)	(-1.50, 0.21)	(-0.38, 0.42)	(-0.54, 0.29)
Month 12	-0.41	-0.92	-1.95	1.57	-0.64	-0.31	-0.32
	(-1.45, 0.64)	(-4.14, 2.30)	(-4.90, 0.99)	(-3.37, 6.50)	(-1.49, 0.21)	(-0.71, 0.10)	(-0.74, 0.10)
Month 15	0.07	-1.71	-0.41	2.15	-0.60	-0.44*	-0.35
	(-0.97, 1.10)	(-4.95, 1.54)	(-3.35, 2.53)	(-2.82, 7.12)	(-1.46, 0.26)	(-0.85, -0.03)	(-0.77, 0.07)
Month 18	-0.69	-2.47	-1.33	1.25	-0.97*	-0.74***	-0.58**
	(-1.75, 0.38)	(-5.79, 0.84)	(-4.33, 1.67)	(-3.88, 6.38)	(-1.87, -0.08)	(-1.15, -0.33)	(-1.00, -0.16)
Baseline value	9.05***	0.20**	-0.08	0.20	0.24	0.35***	0.36***
	(7.05, 11.05)	(0.05, 0.35)	(-0.27, 0.11)	(-0.01, 0.41)	(-0.06, 0.54)	(0.24, 0.47)	(0.25, 0.48)
Constant	-5.81***	4.63**	4.14***	22.76***	2.78**	3.50***	3.33***
	(-7.55, -4.06)	(1.56, 7.69)	(1.72, 6.56)	(14.89, 30.63)	(0.91, 4.66)	(2.69, 4.32)	(2.50, 4.17)
Observations (n)	966	211	210	211	182	965	965
Persons (n)	171	46	46	46	40	171	171

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test); 95% Confidence Intervals in parentheses

^Higher number indicates greater impact

Table 1.D.2. Employment and Labor Market Outcomes Over Time: Complete Case

	Employment and Labor Market Outcomes						
Variables	Employed	Missed work due to health	Missed work other reasons	Actual hours worked	Impact of Health on Work Productivity (0-10)^	Impact of Health on Regular Activities (0-10)^	Impact of Health on Overall Productivity^
Service Dog	**-0.53 (-2.51, 1.44)**	**-1.40 (-6.40, 3.60)**	**-1.25 (-5.64, 3.15)**	**-0.02 (-8.53, 8.49)**	**-0.94 (-2.58, 0.69)**	**-0.28 (-1.07, 0.50)**	**-0.15 (-0.96, 0.66)**
Month 6	-0.84 (-2.61, 0.92)	-0.35 (-4.50, 3.79)	0.80 (-2.89 - 4.48)	0.01 (-6.35, 6.38)	-0.60 (-1.71, 0.51)	-0.18 (-0.78, 0.42)	-0.06 (-0.68, 0.56)
Month 9	-1.31 (-3.16, 0.54)	2.27 (-2.08, 6.63)	-2.78 (-6.65, 1.09)	-1.33 (-8.04, 5.39)	-0.88 (-2.06, 0.30)	0.31 (-0.30, 0.91)	0.27 (-0.36, 0.89)
Month 12	-1.06 (-2.92, 0.80)	-0.44 (-4.82, 3.94)	-2.73 (-6.70, 1.23)	-1.90 (-8.68, 4.87)	-1.26* (-2.45, -0.07)	-0.16 (-0.78, 0.45)	-0.35 (-0.98, 0.28)
Month 15	-1.51 (-3.44, 0.42)	-1.91 (-6.44, 2.61)	0.73 (-3.29, 4.75)	-0.14 (-7.13, 6.84)	-1.00 (-2.24, 0.23)	-0.59 (-1.21, 0.03)	-0.42 (-1.06, 0.22)
Month 18	-2.01* (-3.98, -0.05)	-2.78 (-7.30, 1.75)	-1.52 (-5.54, 2.50)	-3.42 (-10.41, 3.56)	-2.01** (-3.26, -0.75)	-0.87** (-1.49, -0.25)	-0.79* (-1.43, -0.14)
Interaction Terms							
Service Dog * Month 6	**1.06 (-1.12, 3.24)**	**1.65 (-4.68, 7.98)**	**-2.44 (-8.07, 3.19)**	**5.00 (-4.65, 14.65)**	**0.58 (-1.14 - 2.29)**	**-0.16 (-0.96, 0.64)**	**-0.31 (-1.13, 0.52)**
Service Dog * Month 9	**1.46 (-0.80, 3.71)**	**-4.47 (-11.00, 2.05)**	**3.23 (-2.56, 9.03)**	**7.09 (-2.95, 17.13)**	**0.55 (-1.23, 2.33)**	**-0.51 (-1.32, 0.30)**	**-0.71 (-1.54, 0.13)**
Service Dog * Month 12	**1.00 (-1.27, 3.27)**	**-1.02 (-7.56, 5.52)**	**1.53 (-4.34, 7.39)**	**7.69 (-2.39, 17.77)**	**1.39 (-0.38, 3.16)**	**-0.26 (-1.07, 0.56)**	**0.05 (-0.80, 0.89)**
Service Dog * Month 15	**2.31 (-0.02, 4.64)**	**0.40 (-6.19, 6.98)**	**-2.29 (-8.15, 3.56)**	**5.23 (-4.90, 15.36)**	**0.92 (-0.86, 2.70)**	**0.27 (-0.56, 1.09)**	**0.11 (-0.74, 0.95)**
Service Dog * Month 18	**1.95 (-0.40, 4.31)**	**0.59 (-6.14, 7.33)**	**0.32 (-5.66, 6.31)**	**10.43 (-0.06, 20.91)**	**2.25* (0.39, 4.11)**	**0.23 (-0.60, 1.05)**	**0.35 (-0.50, 1.20)**
Baseline value of outcome	9.29*** (7.05, 11.54)	0.20** (0.06, 0.35)	-0.08 (-0.28, 0.12)	0.20 (-0.00, 0.39)	0.24 (-0.02, 0.50)	0.35*** (0.24, 0.47)	0.36*** (0.25, 0.48)
Constant	-5.17*** (-7.15, -3.19)	4.42* (1.01, 7.82)	4.14** (1.28, 7.01)	25.05*** (17.17, 32.94)	3.15*** (1.43, 4.88)	3.46*** (2.60, 4.32)	3.28*** (2.40, 4.15)
Observations (n)	966	211	210	211	182	965	965
Persons (n)	171	46	46	46	40	171	171

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test); 95% Confidence Intervals in parentheses

^Higher number indicates greater impact

Table 1.D.3. Employment and Labor Market Outcomes: Multiple Imputation

	Employment and Labor Market Outcomes						
Variables	Employed	Missed work due to health	Missed work other reasons	Actual hours worked	Impact of Health on Work Productivity (0-10)^	Impact of Health on Regular Activities (0-10)^	Impact of Health on Overall Productivity^
Service Dog	**0.70**	**-2.22**	**-1.81**	**2.98**	**-0.53**	**-0.88***	**-0.84***
	(-0.69, 2.09)	**(-5.33, 0.88)**	**(-4.39, 0.76)**	**(-1.73, 7.69)**	**(-2.22, 1.16)**	**(-1.57, -0.19)**	**(-1.54, -0.13)**
Month 6	-0.14	0.17	-0.36	2.25	-0.19	-0.14	-0.09
	(-1.16, 0.89)	(-2.72, 3.05)	(-3.19, 2.46)	(-1.33, 5.84)	(-1.12, 0.74)	(-0.54, 0.26)	(-0.50, 0.32)
Month 9	-0.41	0.66	-1.21	2.10	-0.12	0.24	0.12
	(-1.45, 0.62)	(-2.37, 3.6948)	(-4.09, 1.67)	(-1.56, 5.75)	(-1.07, 0.83)	(-0.16, 0.64)	(-0.29, 0.53)
Month 12	-0.56	-0.50	-1.43	2.05	-0.10	0.06	0.07
	(-1.59, 0.48)	(-3.58, 2.57)	(-4.44, 1.58)	(-1.59, 5.70)	(-1.04, 0.85)	(-0.34, 0.46)	(-0.34, 0.48)
Month 15	-0.14	-0.66	1.03	3.11	-0.15	0.03	0.13
	(-1.16, 0.89)	(-3.85, 2.52)	(-1.99, 4.05)	(-0.55, 6.77)	(-1.10, 0.80)	(-0.37, 0.43)	(-0.28, 0.54)
Month 18	-0.85	-1.83	-0.04	2.23	0.07	-0.17	-0.02
	(-1.90, 0.21)	(-4.93, 1.28)	(-3.15, 3.06)	(-1.50, 5.96)	(-0.90, 1.04)	(-0.57, 0.23)	(-0.43, 0.39)
Baseline value of outcome	10.05***	0.18*	-0.06	0.21*	0.22	0.29***	0.28***
	(8.26, 11.83)	(0.03, 0.33)	(-0.27, 0.14)	(0.04, 0.38)	(-0.06, 0.51)	(0.17, 0.42)	(0.16, 0.41)
Constant	-6.24***	4.96**	4.35***	22.15***	3.96***	4.36***	4.31***
	(-7.81, -4.67)	(1.88, 8.03)	(1.85, 6.85)	(16.11, 28.18)	(1.86, 6.06)	(3.44, 5.27)	(3.37, 5.25)
Observations (n)	1,086	256	255	257	257	1,086	1,086
Persons (n)	181	50	50	50	50	181	181

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test); 95% Confidence Intervals in parentheses
^Higher number indicates greater impact

Table 1.D.4. Employment and Labor Market Outcomes Over Time: Multiple Imputation

	Employment and Labor Market Outcomes						
Variables	Employed	Missed work due to health	Missed work other reasons	Actual hours worked	Impact of Health on Work Productivity (0-10)^	Impact of Health on Regular Activities (0-10)^	Impact of Health on Overall Productivity^
Service Dog	**-0.48 (-2.41, 1.45)**	**-1.24 (-6.04, 3.57)**	**-1.24 (-5.72, 3.25)**	**-0.59 (-7.10, 5.93)**	**-0.19 (-2.24, 1.86)**	**-0.58 (-1.44, 0.28)**	**-0.50 (-1.38, 0.38)**
Month 6	-0.81 (-2.60, 0.97)	-0.44 (-4.36, 3.47)	0.49 (-3.18, 4.16)	0.67 (-4.15, 5.49)	-0.07 (-1.32, 1.17)	0.02 (-0.56, 0.61)	0.15 (-0.45, 0.76)
Month 9	-1.25 (-3.07, 0.57)	2.72 (-1.52, 6.95)	-2.33 (-6.13, 1.48)	0.38 (-4.51, 5.27)	0.52 (-0.74, 1.78)	0.56 (-0.03, 1.15)	0.56 (-0.04, 1.16)
Month 12	-1.25 (-3.07, 0.57)	0.20 (-3.86, 4.26)	-1.86 (-5.94, 2.22)	0.22 (-4.64, 5.07)	-0.05 (-1.30, 1.21)	0.33 (-0.25, 0.92)	0.23 (-0.38, 0.83)
Month 15	-1.70 (-3.55, 0.16)	-0.09 (-4.47, 4.29)	2.67 (-1.41, 6.75)	1.79 (-3.16, 6.75)	-0.00 (-1.28, 1.28)	0.11 (-0.48, 0.69)	0.2857 (-0.32, 0.89)
Month 18	-2.13* (-4.01, -0.25)	-1.45 (-5.66, 2.76)	0.46 (-3.78, 4.69)	-0.39 (-5.34, 4.56)	0.05 (-1.22, 1.33)	-0.05 (-0.63, 0.54)	0.06 (-0.54, 0.66)
Interaction Terms							
Service Dog * Month 6	**1.03 (-1.17, 3.23)**	**1.49 (-4.76, 7.74)**	**-2.02 (-7.66, 3.63)**	**3.83 (-3.55, 11.21)**	**-0.28 (-2.19, 1.63)**	**-0.31 (-1.11, 0.49)**	**-0.46 (-1.29, 0.36)**
Service Dog * Month 9	**1.25 (-0.98, 3.49)**	**-4.65 (-11.35, 2.06)**	**2.59 (-3.20, 8.39)**	**4.25 (-3.29, 11.78)**	**-1.52 (-3.46, 0.43)**	**-0.60 (-1.40, 0.20)**	**-0.82 (-1.64, 0.00)**
Service Dog * Month 12	**1.03 (-1.21, 3.27)**	**-1.57 (-7.82, 4.68)**	**0.94 (-5.02, 6.91)**	**4.42 (-3.09, 11.94)**	**-0.11 (-2.05, 1.84)**	**-0.51 (-1.31, 0.29)**	**-0.29 (-1.11, 0.53)**
Service Dog * Month 15	**2.32* (0.06, 4.58)**	**-1.16 (-7.68, 5.37)**	**-3.72 (-9.54, 2.11)**	**3.21 (-4.31, 10.72)**	**-0.33 (-2.27, 1.61)**	**-0.14 (-0.94, 0.66)**	**-0.30 (-1.12, 0.53)**
Service Dog * Month 18	**1.91 (-0.38, 4.19)**	**-0.85 (-7.22, 5.53)**	**-1.23 (-7.49, 5.03)**	**6.38 (-1.32, 14.07)**	**0.06 (-1.93, 2.06)**	**-0.23 (-1.03, 0.57)**	**-0.14 (-0.96, 0.68)**
Baseline value of outcome	10.42*** (8.57, 12.26)	0.18** (0.05, 0.32)	-0.06 (-0.27, 0.15)	0.21** (0.05, 0.37)	0.23 (-0.05, 0.51)	0.29*** (0.17, 0.42)	0.28*** (0.16, 0.41)
Constant	-5.65*** (-7.34, -3.96)	4.48** (1.24, 7.71)	4.11** (1.14, 7.08)	23.61*** (17.51, 29.70)	3.79*** (1.68, 5.90)	4.20*** (3.24, 5.16)	4.13*** (3.15, 5.11)
Observations (n)	1,086	256	255	257	257	1,086	1,086
Persons (n)	181	50	50	50	50	181	181

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test); 95% Confidence Intervals in parentheses

^Higher number indicates greater impact

Tables 1.E. Pre-post Analysis of VA Utilization and Costs

Table 1.E.1. Pre-post Analysis of VA Utilization: Negative Binomial Model

	VA Utilization Observation (n) = 2,170; Persons (n) = 181							
Variables	Outpatient Medical/Surgical	Outpatient Pharmacy	Outpatient mental health	Outpatient Substance Abuse	Outpatient Other	Outpatient Days	Inpatient Length of Stay	Inpatient Admissions
Post-period utilization	**-0.08**	**-0.01**	**-0.24*****	**0.00**	**-0.10**	**-0.09*****	**0.20**	**0.31**
	(0.05)	**(0.03)**	**(0.05)**	**(0.23)**	**(0.05)**	**(0.03)**	**(0.36)**	**(0.39)**
Service dog	-0.10	-0.10	-0.01	0.69	-0.12	-0.01	0.51	0.42
	(0.10)	(0.12)	(0.09)	(0.37)	(0.10)	(0.08)	(0.40)	(0.46)
Interaction of post-period * service dog	0.04	0.02	0.02	0.05	0.04	0.03	-0.08	-0.06
	(0.07)	(0.04)	(0.06)	(0.31)	(0.07)	(0.04)	(0.47)	(0.51)
VA Site 584	0.15	-0.10	-0.19	1.50***	-0.34**	-0.20*	0.38	0.70
	(0.11)	(0.14)	(0.10)	(0.40)	(0.11)	(0.09)	(0.37)	(0.40)
VA Site 648	-0.15	-0.05	-0.01	-0.36	-0.39**	-0.25**	-0.05	0.21
	(0.13)	(0.17)	(0.11)	(0.37)	(0.13)	(0.10)	(0.45)	(0.48)
Male	0.05	0.09	-0.11	0.34	0.04	0.09	0.28	0.14
	(0.12)	(0.16)	(0.11)	(0.43)	(0.12)	(0.09)	(0.40)	(0.45)
Constant	1.31***	4.53***	1.58***	-2.31***	1.23***	2.40***	-4.26***	-2.02**
	(0.15)	(0.46)	(0.13)	(0.62)	(0.14)	(0.11)	(0.52)	(0.71)

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test); standard errors in parentheses

Table 1.E.2. Pre-post Analysis of VA Utilization: Negative Binomial Model with Fixed Effects

	VA Utilization Observation (n) = 2,170; Persons (n) = 181							
Variables	Outpatient Medical/Surgical	Outpatient Pharmacy	Outpatient Mental Health	Outpatient Substance Use	Outpatient Other	Outpatient Days	Inpatient Length of Stay	Inpatient Admissions
Post-period utilization	**-0.08***	**-0.01**	**-0.24*****	**0.00**	**-0.10***	**-0.09*****	**0.20**	**0.31**
	(0.05)	**(0.03)**	**(0.05)**	**(0.23)**	**(0.05)**	**(0.03)**	**(0.36)**	**(0.40)**
Service dog	-0.10	-0.10	-0.01	0.69*	-0.12	-0.01	0.51	0.42
	(0.10)	(0.13)	(0.09)	(0.37)	(0.10)	(0.08)	(0.40)	(0.46)
Interaction of post-period * service dog	0.04	0.02	0.02	0.05	0.04	0.03	-0.08	-0.06
	(0.07)	(0.04)	(0.06)	(0.31)	(0.07)	(0.04)	(0.47)	(0.51)
VA Site 584	0.15	-0.10	-0.19*	1.50***	-0.34***	-0.20**	0.38	0.70*
	(0.11)	(0.14)	(0.10)	(0.40)	(0.11)	(0.09)	(0.37)	(0.40)
VA Site 648	-0.15	-0.05	-0.01	-0.36	-0.39***	-0.26***	-0.05	0.21
	(0.13)	(0.17)	(0.11)	(0.37)	(0.13)	(0.10)	(0.45)	(0.48)
Male	0.05	0.09	-0.11	0.34	0.04	0.09	0.28	0.14
	(0.12)	(0.16)	(0.11)	(0.43)	(0.12)	(0.09)	(0.40)	(0.45)
Constant	1.31***	4.53***	1.58***	-2.31***	1.23***	2.40***	-4.26***	-2.02***
	(0.15)	(0.46)	(0.13)	(0.62)	(0.14)	(0.12)	(0.52)	(0.71)

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test); standard errors in parentheses

Table 1.E.3. Pre-post Analysis of VA Utilization: Linear Model with Random Effects

	VA Utilization Observation (n) = 2,170; Persons (n) = 181							
Variables	Outpatient Medical/ Surgical	Outpatient Pharmacy	Outpatient mental health	Outpatient Substance Use	Outpatient Other	Outpatient Days	Inpatient Length of Stay	Inpatient Admissions
Post-period utilization	**-0.29**	**-0.08**	**-1.06*** **	**-0.05**	**-0.14**	**-1.09** **	**0.17**	**0.01**
	(0.17)	**(0.17)**	**(0.24)**	**(0.10)**	**(0.21)**	**(0.37)**	**(0.27)**	**(0.01)**
Service dog	-0.79	-0.63	1.02	-0.01	-0.25	-0.77	0.20	0.01
	(0.41)	(0.78)	(0.75)	(0.21)	(0.46)	(1.28)	(0.37)	(0.02)
Interaction of post-period * service dog	0.14	0.15	-0.15	0.06	0.02	0.38	0.20	0.01
	(0.23)	(0.23)	(0.33)	(0.13)	(0.29)	(0.50)	(0.37)	(0.02)
VA Site 584	0.99*	-0.03	-1.81*	0.32	0.45	-0.50	0.40	0.03
	(0.45)	(0.88)	(0.84)	(0.22)	(0.50)	(1.43)	(0.37)	(0.02)
VA Site 648	-0.52	0.49	-0.35	0.29	-0.57	-0.52	-0.29	-0.00
	(0.51)	(1.00)	(0.95)	(0.25)	(0.57)	(1.63)	(0.42)	(0.02)
Male	-0.75	0.15	-2.30*	0.14	-0.14	-2.24	0.05	0.00
	(0.50)	(0.97)	(0.92)	(0.25)	(0.55)	(1.57)	(0.41)	(0.02)
Constant	4.08***	6.73***	7.66***	0.06	3.52***	17.66***	0.22	0.02
	(0.56)	(1.08)	(1.03)	(0.28)	(0.62)	(1.75)	(0.47)	(0.02)

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test); standard errors in parentheses

Table 1.E.4. Pre-post Analysis of VA Costs: Linear Model with Random Effects

	VA Costs Observation (n) = 2,170; Persons (n) = 181										
Variables	Total	Outpatient Medical/ Surgical	Outpatient Pharmacy	Outpatient Mental Health	Outpatient Substance Use	Outpatient Other	Outpatient Total	Inpatient Medical/ Surgical	Inpatient Mental Health	Inpatient Other	Inpatient Total
Post-period costs	**-886.62***	**-107.47**	**81.67**	**-492.79*****	**-4.85**	**-67.87**	**-592.22****	**-267.43**	**-148.62**	**122.63**	**-293.88**
	(424.58)	**(110.08)**	**(42.87)**	**(98.85)**	**(26.03)**	**(82.32)**	**(199.62)**	**(243.48)**	**(216.28)**	**(140.74)**	**(369.94)**
Service Dog	320.66	-189.39	103.03	321.74	20.91	36.77	293.04	-219.54	183.28	63.89	27.63
	(762.92)	(196.28)	(110.03)	(273.18)	(45.62)	(139.07)	(497.42)	(254.71)	(232.99)	(188.50)	(430.87)
Interaction post-period * service dog	327.23	36.90	-56.14	14.95	12.60	28.35	37.59	229.43	-187.67	246.91	289.13
	(579.67)	(150.29)	(58.53)	(134.95)	(35.54)	(112.39)	(272.53)	(332.44)	(295.30)	(192.15)	(505.09)
VA Station 584	264.62	616.31**	-83.30	-633.96*	37.44	54.33	-9.73	276.91	-82.26	80.29	274.66
	(804.53)	(206.72)	(120.90)	(301.73)	(47.90)	(145.03)	(545.31)	(220.16)	(205.58)	(184.93)	(398.15)
VA Station 648	-88.66	291.37	72.54	103.68	54.29	-324.64*	197.19	237.59	-455.60	-67.80	-285.83
	(917.99)	(235.87)	(137.96)	(344.31)	(54.65)	(165.48)	(622.25)	(251.12)	(234.50)	(210.98)	(454.19)
Male	-2,034.17*	-321.03	38.98	-1,365.35***	33.69	-163.00	-1,776.87**	178.36	-673.44**	237.95	-257.21
	(884.72)	(227.32)	(132.96)	(331.83)	(52.67)	(159.49)	(599.69)	(242.02)	(226.01)	(203.34)	(437.74)
Constant	6,833.87***	1,367.94***	372.44*	3,001.63***	13.43	1,023.04***	5,778.85***	248.02	984.01***	-177.39	1,054.82*
	(1,004.51)	(258.20)	(149.10)	(371.56)	(59.88)	(181.71)	(672.96)	(294.87)	(273.12)	(236.37)	(519.78)

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test); standard errors in parentheses

Table 1.E.5. Pre-post Analysis of VA Costs: GEE Model

	VA Costs Observation (n) = 2,170; Persons (n) = 181										
Variables	Total	Outpatient Medical/ Surgical	Outpatient Pharmacy	Outpatient Mental Health	Outpatient Substance Use	Outpatient Other	Outpatient Total	Inpatient Medical/ Surgical	Inpatient Mental Health	Inpatient Other	Inpatient Total
Post-period costs	**-0.19***	**-0.11**	**0.17**	**-0.37*****	**-0.50**	**-0.13**	**-0.16*****	**did not converge**	**did not converge**	**did not converge**	**-0.40**
	(0.08)	**(0.09)**	**(0.09)**	**(0.06)**	**(0.40)**	**(0.10)**	**(0.05)**				**(0.49)**
Service Dog	0.06	-0.10	0.23	0.13	0.44	0.06	0.06				0.27
	(0.15)	(0.15)	(0.22)	(0.14)	(0.61)	(0.16)	(0.11)				(0.53)
Interaction post-period * service dog	0.09	0.04	-0.12	0.09	0.64	0.06	0.04				0.33
	(0.12)	(0.12)	(0.12)	(0.08)	(0.54)	(0.13)	(0.06)				(0.66)
VA Station 584	0.10	0.49**	-0.16	-0.35*	1.09	0.09	0.03				0.48
	(0.15)	(0.16)	(0.24)	(0.15)	(0.63)	(0.17)	(0.12)				(0.47)
VA Station 648	0.03	0.26	0.17	0.18	1.21	-0.45*	0.08				-0.38
	(0.18)	(0.18)	(0.27)	(0.17)	(0.72)	(0.19)	(0.14)				(0.53)
Male	-0.36*	-0.24	0.13	-0.71***	1.28	-0.19	-0.38**				-0.09
	(0.17)	(0.17)	(0.26)	(0.17)	(0.69)	(0.19)	(0.14)				(0.51)
Constant	8.80***	7.16***	5.88***	8.04***	2.35**	6.94***	8.66***				6.61***
	(0.19)	(0.20)	(0.29)	(0.19)	(0.79)	(0.21)	(0.15)				(0.62)

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test); standard errors in parentheses

2. Long-Term Cost-Effectiveness: Supplemental Information (Chapter 2)

2.A. Detailed Methods

Table 2.A1. Impact Inventory

Sector	Type of Impact (Add additional domains, as relevant)	Included in This Analysis from […] Perspective?	
		Health Care Sector	Societal
Health Outcomes	Longevity effects	X	X
	Health-related quality of life effects	X	X
	Adverse events	X	X
Medical Costs	Paid by third-party payers	X	X
	Paid by patients out-of-pocket	☐	☐
	Future related medical costs	X	X
	Future unrelated medical costs	☐	☐
Health-Related Costs	Patient time costs	NA	X
	Unpaid caregiver-time costs	NA	☐
	Transportation costs	NA	☐
Productivity	Labor market earnings lost	NA	X
	Cost of unpaid lost productivity due to illness	NA	X
	Cost of uncompensated household production	NA	☐
Consumption	Future consumption unrelated to health	NA	☐
Social services	Cost of social services as part of intervention	NA	☐
Legal/Criminal Justice	Number of crimes related to intervention	NA	☐
	Cost of crimes related to intervention	NA	☐
Education	Impact of intervention on educational achievement of population	NA	☐
Housing	Cost of home improvements, remediation	NA	☐
Environment	Production of toxic waste pollution by intervention	NA	☐
Other	Other impacts (if relevant)	NA	☐

NA: not applicable

Adapted from Sanders et al[81]

Description evLYG Calculations

The cost per evLYG considers any extension of life at the same "weight" no matter what treatment is being evaluated. Below are the stepwise calculations used to derive the evLYG.

1. First, we attribute a utility of 0.851, the age- and gender-adjusted utility of the general population in the US that are considered healthy. [82]

2. For each cycle (Cycle I) in the model where using the intervention results in additional years of life gained, we multiply this general population utility with the additional life years gained (ΔLYG).

3. We sum the product of the life years and average utility (cumulative LYs/cumulative QALYs) for Cycle I in the comparator arm with the value derived in Step 2 to derive the equal value of life years (evLY) for that cycle.

4. If no life years were gained using the intervention versus the comparator, we use the conventional utility estimate for that Cycle I.

5. The total evLY is then calculated as the cumulative sum of QALYs gained using the above calculations for each arm.

6. We use the same calculations in the comparator arm to derive its evLY.

Finally, the evLYG is the incremental difference in evLY between the intervention and the comparator arms. Because the intervention was not associated with any life extension, the evLYG was equivalent to the QALY.

Model Inputs

Table 2.A2 presents a detailed break-down of the average VA pricing per contract, stratified by SERV and EMOT.

Table 2.A2. EMOT and SERV Intervention Related Costs from VA Trial

	Types of Costs	Average Cost
Service Dog (SERV)		
	Vendor Purchase of Candidate Service Dog	$9,160.80
	Service Dog Training	10, 413.18
	Veteran travel to be paired with a service dog	2,150.00
	Veterinary care for dog	1,330.39
	Food for dog	286.41
	Housing/ routine care for dog	2,339.22
Total Cost		**$25,680.00**

	Types of Costs	Average Cost
Emotional Support Dog (EMOT)		
	Vendor Purchase of Candidate Emotional Support Dog	$5,865.53
	Emotional Support Dog Training	6,036.69
	Veterinary care for dog	1,330.39
	Food for dog	286.41
	Housing/ routine care for dog	2,339.22
Total Cost		**$15,858.24**

Table 2.A3. Age- and Sex-Adjusted Mortality

Age	Probability of Death – Male	Probability of Death - Female
18	0.000858	0.000336
19	0.000999	0.000379
20	0.001146	0.000425
21	0.001288	0.000472
22	0.001407	0.000515
23	0.001494	0.000551
24	0.001556	0.000582
25	0.00161	0.000612
26	0.001665	0.000646
27	0.001717	0.000684
28	0.001767	0.000729
29	0.001817	0.000779
30	0.001865	0.000833
31	0.001911	0.000887
32	0.00196	0.000939
33	0.002014	0.000988
34	0.002071	0.001034
35	0.002138	0.001085
36	0.002211	0.001143
37	0.002279	0.001205
38	0.002342	0.001271
39	0.002405	0.001345
40	0.002482	0.001429
41	0.002583	0.001524
42	0.00271	0.00163
43	0.00287	0.001748
44	0.003064	0.001881
45	0.003285	0.002029
46	0.003538	0.002195
47	0.003834	0.002386
48	0.004178	0.002605
49	0.004569	0.002851

Age	Probability of Death – Male	Probability of Death - Female
50	0.004997	0.003118
51	0.005462	0.003403
52	0.005971	0.003714
53	0.006526	0.004052
54	0.007125	0.004415
55	0.007766	0.004813
56	0.008445	0.005233
57	0.009156	0.005647
58	0.009897	0.006043
59	0.010671	0.006441
60	0.011519	0.006886
61	0.012419	0.007391
62	0.013307	0.007931
63	0.014164	0.008508
64	0.015032	0.009142
65	0.016013	0.009874
66	0.017138	0.010717
67	0.018362	0.01166
68	0.019693	0.012711
69	0.021174	0.013894
70	0.022889	0.015285
71	0.024869	0.016878
72	0.027095	0.018607
73	0.029587	0.020466
74	0.032394	0.022522
75	0.035668	0.024929
76	0.039396	0.027729
77	0.043453	0.030855
78	0.047826	0.034321
79	0.052649	0.038211
80	0.058206	0.042771
81	0.064581	0.047992
82	0.071657	0.053678
83	0.079465	0.05981
84	0.088141	0.066584
85	0.097854	0.074258
86	0.108747	0.083053
87	0.120919	0.093123
88	0.134425	0.10454
89	0.149273	0.117305
90	0.165452	0.131392
91	0.182935	0.146753
92	0.201679	0.163331
93	0.221637	0.181064
94	0.242747	0.199886
95	0.263672	0.218908

Age	Probability of Death – Male	Probability of Death - Female
96	0.284014	0.237815
97	0.303355	0.256265
98	0.321268	0.273894
99	0.337332	0.290328
100	0.354198	0.307747

2.B. Results

QALY Shortfalls

One important contextual consideration to consider is the argument that society should give preference to treatments for patients with more severe conditions,[83] and that giving priority to treatments according to "lifetime burden of illness" or "need" best represents the ethical instincts of a society or other decision-makers.[84,85] To inform this contextual consideration, ICER provides empirical results for the absolute QALY shortfall and proportional QALY shortfall. The absolute QALY shortfall is defined as the total absolute amount of future health patients with a condition are expected to lose without the treatment that is being assessed.[86] The ethical consequences of using absolute QALY shortfall to prioritize treatments is that conditions that cause early death or that have very serious lifelong effects on quality of life receive the greatest prioritization. Thus, certain kinds of treatments, such as treatments for rapidly fatal conditions of children, or for lifelong disabling conditions, score highest on the scale of absolute QALY shortfall.

The proportional QALY shortfall is measured by calculating the proportion of the total QALYs of remaining life expectancy that would be lost due to untreated illness.[87,88] The proportional QALY shortfall reflects the ethical instinct to prioritize treatments for patients whose illness would rob them of a large percentage of their expected remaining lifetime. As with absolute QALY shortfall, rapidly fatal conditions of childhood have high proportional QALY shortfalls, but the highest numbers can also often arise from severe conditions among the elderly who may have only a few years left of average life expectancy but would lose much of that to the illness without treatment.

For this population of Veterans with PTSD, the absolute shortfall was estimated to be 9.02 QALYs, with a proportional shortfall of 0.36, representing a loss of 36% of total quality-adjusted life expectancy (QALE) relative to individuals without the condition. To provide some anchoring of these results, we also present a league table of absolute and proportional QALY shortfalls for a variety of conditions from prior ICER reports (Table 2.B1), using a burden of disease calculator developed by Dutch investigators (https://imta.shinyapps.io/iDBC/) that allows for calculation of absolute and proportional QALY shortfalls under different assumptions.[85]

Table 2.B1. League Table of Absolute and Proportional QALY Shortfalls for Selected Conditions

	From ICER Reports			From iDBC tool[89]	
Condition	Age	% Male	Total Undiscounted QALYs with Standard of Care	Absolute Shortfall	Proportional Shortfall
Veterans with PTSD	50.6	80%	16.22 (No Dog)	9.02	0.36
Heterozygous FH with ASCVD	62	50	14.1	3.09	0.18
Secondary Prevention for ASCVD	66	61	13.9	0.54	0.04
Cystic Fibrosis	2	52	25.8	42.3	0.62
Secondary Progressive Multiple Sclerosis	48	39	3.0	24.5	0.89
Hemophilia A	18	100	38.6	13.3	0.26
Treatment-Resistant Major Depression	46	33	20.5	8.7	0.30
Moderate-to-Severe Ulcerative Colitis	40	59	27.4	6.2	0.19
BCG-Unresponsive High-Risk NMIBC	72	80	4.94	5.7	0.54

ASCVD: Atherosclerotic Cardiovascular Disease, BCG: Bacillus Calmette-Guerin FH: Familial Hypercholesterolemia, iDBC: Individual Driving Cycle Builder, NMIBC: non-muscular invasive bladder cancer, PTSD: Post-traumatic stress disorder, QALY: quality-adjusted life year

2.B2. Sensitivity Analyses

To demonstrate effects of uncertainty on both costs and health outcomes, we varied input parameters using available measures of parameter uncertainty (i.e., standard errors) or reasonable ranges to evaluate changes in cost per additional QALY for SERV vs. EMOT. The main report presents the tornado diagram that identifies key drivers of variability and uncertainty; however, Table 2.B2 provides supporting information for this diagram including the specific inputs values that were varied and the results incremental cost-effectiveness ratios.

Table 2.B2. Tornado Diagram Inputs and Results for [Intervention] versus [Comparator]

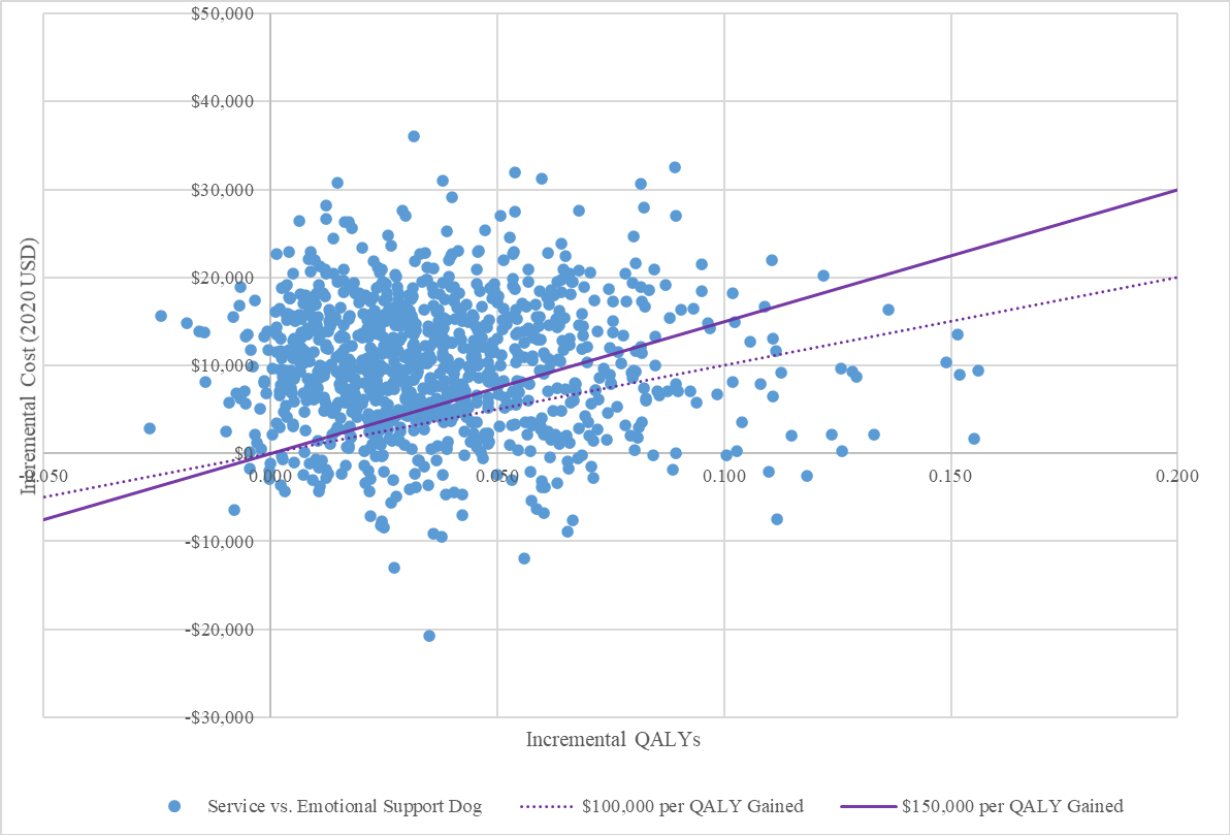
	Lower ICER	Upper ICER	Lower Input*	Upper Input*
Duration of pairing SERV	$222,208	$336,923	5.04	8.96
Cost of EMOT (wo insurance)	$91,565	$407,275	9641.78	22074.22
Cost of annual insurance	$82,208	$416,633	1620.10	3709.10
Cost of SERV (wo insurance)	-$6,206	$505,046	15613.62	35746.38
Utility for PTSD for one unit change inPCL-4	$132,530	$2,113,440	-0.0038	-0.0002
PCL-5 Difference for SERV vs EMOT	$129,434	$3,417,182	-7.13	-0.27

EMOT: Emotional support dog, ICER: incremental cost-effectiveness results, PCL-4: PTSD Civilian Checklist 4, PCL-5: PTSD Civilian Checklist 5, PTSD: Post-traumatic stress disorder, SERV: Service dog, wo: without

* Note lower input may reflect either upper or lower ICER value depending on the direction that the input has on the ICER output.

Figure 2.A.1. presents our primary incremental results comparing SERV to EMOT.

Figure 2.A.1. Probabilistic Sensitivity Analysis Results: Cost-Effectiveness Cloud Comparing SERV to EMOT



EMOT: Emotional support dog, QALY: quality-adjusted life year, SERV: Service dog

3. Exploratory Pre-Post Analysis (Chapter 1)

Pre-post analysis

Methods

In exploratory analyses, we conducted an observational pre-post analysis of outcomes. We compared outcomes for all participants in the 18 months prior to pairing (pre) and after they received a dog (post) for VA costs and utilization. We evaluated costs pre-post using a linear model with random effects as the main model and with GEE in sensitivity analyses. We evaluated utilization using a negative binomial model (primary model), a negative binomial model with fixed effects (sensitivity analysis), and a linear model with random effects (sensitivity analysis).

Results

In exploratory pre-post analysis of costs and utilization, which combines outcomes for both study groups, outpatient psychiatry/mental health utilization and costs were significantly lower in the post period than the pre period (utilization: beta coefficient -0.24, SE 0.05; costs: -$492.79, SE 98.85; p<0.001 for both). Participants in the post period also experienced significantly fewer outpatient days (beta coefficient -0.09, SE 0.03, p<0.001) and lower outpatient total costs (beta coefficient -592.22, SE 199.62, p<0.01) than participants in the pre period. There were no other significant correlations in pre-post trends. The results are summarized in Table 1.11; Tables 1.E provide the full regression models.

Table 3.A.1. Pre-post analysis of VA Cost and Utilization: Summary Table[a]

	VA Utilization[b] Beta Coefficient (Standard Error)	VA Costs[c] Beta Coefficient (Standard Error)
Total	--	-$ 886.62* (424.58)
Inpatient		
Inpatient Admissions	0.31 (0.39)	-$ 293.88 (369.94)
Inpatient Length of Stay	0.20 (0.36)	--
Inpatient Medical/Surgical	--	-$ -267.43 (243.48)
Inpatient Mental Health	--	-$ 148.62 (216.28)
Inpatient Other	--	$ 122.63 (140.74)
Outpatient		
Outpatient visits	-0.09*** (0.03)	-$ 592.22** (199.62)
Outpatient Medical/Surgical	-0.08 (0.05)	-$ 107.47 (110.08)
Outpatient Pharmacy	-0.01 (0.03)	$ 81.67 (42.87)
Outpatient Mental Health	-0.24*** (0.05)	-$ 492.79*** (98.85)
Outpatient Substance Use	0.00 (0.23)	-$ 4.85 (26.03)
Outpatient Other	-0.10 (0.05)	-$ 67.87 (82.32)
Observations (n)	2,170	2,170

Persons (n)	181	181

*** p<0.001, ** p<0.01, * p<0.05 (two-tailed test)

[a] The full regression results can be found in Tables 1.E.1 and 1.E.4.

[b] VA Utilization data produced using a negative binomial model.

[c] VA Costs data produced using a linear model with person-specific random effects.

All costs adjusted to 2018 dollars.

Discussion

Pre-post analyses indicate that the receipt of a dog, whether EMOT or SERV, was associated with a decrease in outpatient mental health care and experienced fewer outpatient days in the post period. However, we are not able to explain why this happened and this effect should not be taken as causal. One explanation is that both groups saw improvements and decreased use of care in the post period (i.e., regression to the mean). Indeed, this is supported by the first monograph, which found that both groups showed significant improvement in PTSD symptoms over time.

4. Categories of Care Codes for VA Cost and Utilization Data (Chapter 1)

Table 4.A. 1. Categories of Care for VA Cost and Utilization Data

Category of Care	Inpatient Treating Specialty or Outpatient Clinic Stop
Inpatient Medical/Surgical	1-19, 24, 30, 31, 34, 83, 1E, 1F, 1H, 1J, 48-63, 65, 78, 97, 1G
Inpatient Psychiatry/Mental Health	25, 26, 28, 29, 33, 38, 39, 70, 71, 75, 76, 77, 79, 89, 91, 92, 93, 94, 1K, 1L
Inpatient Substance Use Treatment	27, 72, 73, 74, 84, 90, 1M
Inpatient Other	All other treating specialties
Outpatient Medical/Surgical	327, 328, 424, 435, 441, 716, 40, 410, 411, 412, 413, 414, 415, 416, 419, 420, 421, 422, 426, 427, 428, 429, 430, 431, 432, 433, 101, 102, 103, 110, 116, 130, 131, 142, 143, 144, 149, 153, 158, 159, 182, 185, 186, 187, 188, 231, 30, 31, 320, 321, 322, 323, 324, 325, 326, 329, 330, 331, 332, 333, 335, 336, 337, 338, 339, 340, 341, 342, 345, 348, 349, 350, 351, 352, 353, 369, 370, 371, 372, 373, 394, 434, 436, 437, 439, 45, 46, 47, 480, 481, 482, 483, 484, 485, 511, 674, 683, 684, 685, 686, 690, 691, 692, 694, 695, 706, 709, 710, 712
Outpatient Pharmacy	160 / PHA
Outpatient Psychiatry/Mental Health	156, 157, 501, 502, 504-506, 509, 510, 512, 515, 516, 520-522, 524-540, 542, 546, 550-554, 557-559, 561-584, 589-592, 731
Outpatient Substance Use Treatment	507, 508, 513, 514, 517-519, 523, 543-545, 547, 548, 555, 556, 560, 588, 593-599, 707
Outpatient Other	All other clinic stops

5. Public Comments (Chapter 2)

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October 2, 2020

Subject: Input for Assessment of Cost-Effectiveness of Trained Service Dogs for American Veterans with PTSD

Dear Institute for Clinical and Economic Review (ICER),

We are pleased to provide our input for your review addressing the value and benefits of trained service dogs for veterans dealing with post-traumatic stress disorder (PTSD). Our agency continues to provide extensive training and support to these veterans. In conjunction with researchers at the University of Central Florida, we continuously gather data assessing the outcomes for participants in our training program. This is largely done through pretest and posttest assessments which include the PTSD Checklist for DSM-5 (PCL-5) and the Trauma Symptom Inventory (TSI-2). Pretest scores for the PCL-5 and TSI-2 are obtained before each participant's first class and following their final class when they successfully complete the 21-week service dog training program requirements.

We have pretest and posttest data on **182 veterans with PTSD** who have completed our program. Participants in this program consistently report via the PCL-5 and TSI-2 statistically significant improvements in their social/relational functioning and in their mood along with reductions in the PTSD-related difficulties from pretest and posttest. PTSD-related improvements include reductions in intrusive thoughts and avoidance of trauma-related material. They also note decreased hyperarousal, hypervigilance, and avoidance behaviors. Sixty-one percent of participants reported decreased suicidal ideations and behaviors. The data from these assessments continue to demonstrate improvement in the clinical scales measured by the TSI-2 and PCL-5 from pretest to posttest. These results help substantiate the considerable benefits of this program.

Our ongoing outcomes continue to show that this program is an effective nongovernmental partner with governmental agencies including the Veterans Administration (VA) and DoD to increase the capacity and impact of suicide prevention programs. The program is a central part of a broader community-based model to effectively implement evidence-informed mental health and suicide prevention services. The benefits to veterans with PTSD noted in this program provides continuing evidence to support the endorsement and use of service dog training programs like K9P4P as helpful complementary and/or alternative treatment options for some veterans with PTSD. These benefits are most notably evident in the following ways:

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1. They improve participating veteran's quality of life by increasing their social connections and engaging them with other veterans (i.e., heightened camaraderie) along with mitigating their suicide risk factors.
2. They provide an ongoing way to support and intervene with these veterans far before the point of crisis.
3. Participants stay engaged in the program for a minimum of six months along with regular follow-up contact with the agency. Some stay connected with the program for several years after program completion.
4. The program appears to be especially helpful for veterans who drop out or who only minimally participating in standard VA treatments. Participants have shown that they are far more willing to start and complete this service dog program for their PTSD compared to standard trauma treatments.
5. Participating in this program increases these veteran's involvement and engagement in PTSD services provided by the Veterans Administration VA. After completing the service dog program, many veterans also describe an increasing willingness to participate in standard PTSD treatments offered through the VA or their medical provider.
6. The program collaborates with a broad group of agencies (VA, DoD, local/state governments, and local veterans service agencies) to identify and support these veterans.
7. Participants are also provided with individual and group counseling services provided by a licensed therapist as part of the K9P4P program.

The results of our pretest and posttest data reflect ongoing benefits for these veterans associated their participation in our training program. Key outcome results for 182 veterans who have been through our program (from the TSI-2 and PCL-5) are provided below:

90% (n = 182) of participants reported decreased anxious arousal symptoms

88% (n = 182) of participants reported decreased depression symptoms

87% (n = 182) of participants reported decreased anger/irritability symptoms

88% (n =182) of participants reported decreased intrusive PTSD symptoms

85% (n =182) of participants reported decreased defensive avoidance

87% (n = 182) of participants reported decreased dissociative symptoms

Giving Veterans
a Second Chance at Life.

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81% (n = 182) of participants reported decreased somatic preoccupations and distress

61% (n = 182) of participants reported decreased suicidal ideations and behaviors

88% (n = 182) of participants reported decreased difficulties or insecurities of insecure attachment

81% (n = 182) of participants reported decreased tension reduction behaviors

92% (n = 25) of participants reported decreased overall PTSD symptoms (i.e., Total Symptom Severity Score on the PCL-5)

We hope that you will consider these inputs and results when assessing the findings from the recently completed service dog study completed by the U.S. Department of Veterans Affairs (VA). Thank you for this opportunity!

Respectfully,

Ronald Flaville
K9 Partners for Patriots, Inc.
Chief Executive Officer