

Positive Results from the SERVICE study: A Prospective, Non-Interventional, Study Measuring the Effectiveness of the Horse

Sense and Healing (HSH) Program as a Complimentary Treatment for PTSD.

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Background and Rationale

- Since October 2001, over 1.64 million U.S. troops have deployed to Iraq and Afghanistan¹.
- The reported prevalence of PTSD amongst ex-U.S. Service personnel is 14%²
- Although existing data on equine assisted therapy is mainly positive, studies to have not reported statistical significance³
- HSH is a 3-day equine assisted therapy program open to U.S. military service personnel and Emergency First Responders suffering from psychological stress following a traumatic event
- Based on the principals of Join-Up[®], a well-established horse training technique, horses are utilized to encourage participants to establish a trust-based bond
- This aims to introduce new ways of coping by eliminating violence and helping participants regain the ability to trust and communicate
- The SERVICE study aimed to measure the potential benefits of HSH as a complimentary therapy for stress related psychological injury

Methods

- Data was collected over 3 years in this prospective, non-interventional, single center study
- Participants were considered eligible if they met the inclusion/exclusion criteria (Figure 1)
- Assessments were made at Baseline, Day 3 and Day 85
- PTSD symptom severity was assessed via the Impact of Event Scale – Revised (IES-R)
- Quality of Life (QoL) was evaluated using the Quality of Life Enjoyment and Satisfaction Questionnaire-Short Form (QLES-Q-SF)
- Descriptive statistics were utilized to summarize mean scores at each time point and
- Paired sample t-tests assessed the mean change from baseline
- The study was reviewed and approved by an independent ethics review board.

Figure 1: Inclusion/Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> • Participant is enrolled in Horse Sense and Healing • Participant has been in active service in the U.S. Military Forces or has worked as an Emergency First Responder • Participant has, following traumatic event(s), either: <ul style="list-style-type: none"> • Sought medical treatment or consultation for stress related symptoms; • Experienced psychiatric events that have led to the involvement of local law enforcement agencies 	<ul style="list-style-type: none"> • Participant has a formal diagnosis of Schizophrenia or Bi-Polar Disorder • Participant is currently enrolled in a clinical trial in which the investigational medicinal product aims to treat either the causes or symptoms of Post-Traumatic Stress Disorder (PTSD) or Major Depressive Disorder (MDD)

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Results

- Over 3 years, 101 primary participants and 28 caregivers enrolled in the study
- The mean age of participants was 48 and 75.2% were male
- At baseline, participants reported a high burden of illness (Figure 2)
- Statistically significant, clinically meaningful⁴ score improvements were reported in IES-R Total Score and across all domains (Figure 2, Figure 3)
- Significant improvements on QoL were also reported from Baseline to Day 85 (Figure 2)

Figure 2: IES-R and QLES-Q-SF Results

	Baseline	Day 3	Day 85
IES-R	n=101	n=93	n=40
Score decrease demonstrates improvement			
Total Score (0-88)			
Mean (SD)	50.14 (22.08)	29.02 (19.64)	32.53 (20.57)
Mean change from Baseline [95% CI]	n/a	-22.41 [-26.97, -17.84]*	-16.88 [-22.82, -10.93]*
Intrusion (0-4)			
Mean (SD)	2.38 (1.14)	1.13 (0.99)	1.54 (1.07)
Mean change from Baseline [95% CI]	n/a	-1.14 [-1.39, -0.89]*	-0.90 [-1.25, -0.55]*
Hyperarousal (0-4)			
Mean (SD)	2.45 (1.11)	1.23 (0.99)	1.53 (1.07)
Mean change from Baseline [95% CI]	n/a	-1.28 [-1.52, -1.04]*	-0.8 [-1.11, -0.50]*
Avoidance (0-4)			
Mean (SD)	2.07 (1.08)	1.40 (0.98)	1.49 (1.04)
Mean change from Baseline [95% CI]	n/a	-1.05 [-1.32, -0.79]*	-0.95 [-1.34, -0.56]*
QLES-Q-SF	n=101	n=89	n=36
Score increase demonstrates improvement			
Total Transformed Score (0-100)			
Mean (SD)	62.40 (16.0)	73.19 (17.82)	73.81 (13.52)
Mean change from Baseline [95% CI]	n/a	11.07 [7.37, 14.78]*	11.31 [7.01, 15.61]*

* p<0.001

Conclusions

- Given the high level of symptom severity (measured via IES-R) there is clearly a high unmet need within this population
- Score changes in symptom severity a Days 3 and 85 show a clinically meaningful improvement that is higher than comparative clinical literature assessing pharmacological interventions
- QoL and Wellbeing also showed meaningful improvement that was sustained over the 3-month follow-up period
- This is the first study of an animal assisted therapy program to report statistical significance
- HSH is an effective complimentary therapy for PTSD

Figure 3: Mean IES-R Score Over Time

