

# Horsepower - The Effect of Equine Assisted Therapy on Military Veterans with Post-traumatic Stress Disorder

Published: 09-03-2021

Last updated: 08-04-2024

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Anxiety disorders and symptoms
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON51153

### Source

ToetsingOnline

### Brief title

Horsepower

### Condition

- Anxiety disorders and symptoms

### Synonym

Post-traumatic stress disorder

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universiteit Utrecht

**Source(s) of monetary or material Support:** fondsen

## Intervention

**Keyword:** Horse, PTSD, Therapy, Veteran

## Outcome measures

### Primary outcome

The primary study parameters are the subjective welfare parameters that are measured each week in the veterans using questionnaires. These subjective welfare parameters are;

- Change in cognition and mood
- Change in feeling bad about yourself
- Change in feeling guilty
- Change in not being able to trust anybody
- Change in feeling that the world is dangerous
- Change in feeling that the nerve system is destroyed forever
- Participation and interest in activities
- Collaboration with other people
- Feeling positive
- Experiencing satisfaction
- Experiencing happiness
- Finding a purpose / meaning in life
- Having a prospect for the future
- Sleep disturbances and insomnia
- Flashbacks / nightmares
- Stress levels

## Secondary outcome

The secondary study parameters are the objective welfare parameters that are measured each week in the veterans and horses. These objective welfare parameters are;

- Heart rate variability
- Salivary cortisol
- Salivary oxytocin
- Stress related behaviour

## Study description

### Background summary

Existing literature suggests that animal assisted interventions (AAI) could positively affect the welfare of veterans diagnosed with PTSD (O'Haire et al., 2015), but recent research has mainly focused on the use of specially trained PTSD service dogs (reviewed in van Houtert et al., 2018). A relatively new type of therapy is equine-assisted therapy. Although the limited number of studies published on this subject does suggest a positive effect (for example Malinowski et al., 2018), hard evidence of the effectiveness of equine-assisted therapy on veterans diagnosed with PTSD is lacking. Most existing studies have used a large variation of questionnaires or interview techniques to measure the effect of equine-assisted therapy on PTSD symptoms. Although these studies might provide promising results (Johnson et al., 2018, Malinowski et al., 2018), in this study we want to know whether the effects that have been found in previous studies can also be measured in the human body using objective measurements.

Additionally, the already existing studies use different methods of working with horses, so the exact content of equine-assisted therapy that could cause a decrease in PTSD symptoms is unclear. Whereas some studies suggest that simply interacting with the horse can create positive effects, other studies claim that riding is a crucial part of the therapy (Johnson et al., 2018).

Finally, the physiological and behavioural responses of the therapy horses are underexposed in existing research. It is important to look at the responses of the horses, as it is suggested that the mental state of a rider has an effect on the physiology and behaviour of the horse (Nuyts, Exadaktylos & Berckmans, 2013). This means that there might be a relationship between the responses of

the veterans and the responses of the horses, for example increased oxytocin levels in both veterans and horses during positive interactions.

This study will look into the effects of 12 weeks of grouptherapy with horses on military veterans that are diagnosed with PTSD. With the use of objective as well as subjective measurements in veterans and horses this research will investigate whether this form of therapy leads to a decrease in PTSD symptoms and thus an improvement in quality of life of these veterans. The hypothesis of this research is that veterans will experience a decrease in PTSD symptoms and thus improved quality of life after participation in the 12-week grouptherapy program with horses.

## **Study objective**

The primary objective of this study is to measure to what extent a 12-week grouptherapy program with horses leads to an improvement in the quality of life of military veterans that are diagnosed with PTSD. Quality of life will be measured using the following 16 parameters, which are related to the symptoms of PTSD;

- Change in cognition and mood
- Change in feeling bad about yourself
- Change in feeling guilty
- Change in not being able to trust anybody
- Change in feeling that the world is dangerous
- Change in feeling that the nerve system is destroyed forever
- Participation and interest in activities
- Collaboration with other people
- Feeling positive
- Experiencing satisfaction
- Experiencing happiness
- Finding a purpose / meaning in life
- Having a prospect for the future
- Sleep disturbances and insomnia
- Flashbacks / nightmares
- Stress levels

## **Study design**

This study will have a purely observational design using non-invasive measurements and questionnaires. Participants participate in one therapy session per week for a total of twelve weeks. Sessions take place at the location of Stal Groenendaal, which is located at Zevenhuizerstraat 154 in Bunschoten-Spakenburg, the Netherlands. Each session starts at 10:00 and finishes around 15:00. In the morning the participants get an introduction and theory on how to work with the horse. After this interaction each participant will have 15 minutes of free interaction with his or her horse. During this free interaction participants can make a connection with their horse in any way

they want to. After the free interaction participants receive a joint lunch. Thereafter, the participants will have a directed interaction with their horse. During this directed interaction they will have a different assignment each week. The first weeks the assignments will be taking care of the horses and doing groundwork with them, for example letting the horses walk over obstacles such as a plastic sheeting. The last three weeks the participants will also ride the horses. After working with the horses there is time to reflect, share experiences and give feedback to each other.

During the day heart rate of the participants will be measured using a Polar m430 watch. This watch is linked to a Polar H10 transmitter, which is placed in Hylofit electrodes that are attached to an elastic band that is placed around the waist of the participants. The Polar watch and transmitter will save heart rate data of the participants, which enables the researchers to investigate differences in heart rate during the sessions with the horses as well as over the 12 weeks. Besides, participants will wear a small bag around their waist. In this bag an Actigraph GT9X accelerometer is placed, which registers the activity of the veterans during the session with the horses. The researchers will link this data about the activity of the participants to the heart rate data, so that they can determine whether particular increases in heart rate are attributed to physical effort or to mental tension or stress.

Additionally, saliva sampling will be done each week before and after working with the horses in the morning and afternoon. In total four samples will be taken every week for each participant.

Both the free interaction in the morning and the directed interaction in the afternoon will be filmed using Oppo A5 (2020) mobile phones. These mobile phones are limited in such a way that they can only be used for filming. The phones do not have access to the internet, and it is not possible to watch the videos directly on the mobile phones. The videos are only saved on Yoda, which is a protected drive that is used by Utrecht University. The videos will be observed in the program Observer XT 12 in order to observe stress related behaviour in veterans and horses. In order to get their permission, the participants have signed a form before the start of the intervention in which they agree to be filmed (see document E2).

Finally, each week the participants will fill out questionnaires. Two out of the four questionnaires will be filled out each week, the other two questionnaires will be filled out once a month. 12 weeks after the last session the participants will be asked to come to Stal Groenendaal for a follow up measurement, in which they fill in the questionnaires for the last time. One of the questionnaires that will be used is the PCL-5 questionnaire. This questionnaire will also be filled in monthly by a waitlist control group of 24 veterans.

## **Study burden and risks**

The only risk that is associated with participation in this study is that the participants will work with horses. However, the horses that will be used for this study are very calm and reliable. The chance that these horses will

startle is therefore very low. Additionally, experienced supervisors will be present, who can intervene at any time if necessary. The intended benefit in terms of a decrease in PTSD symptoms and improved quality of life will therefore outweigh the small risk that is inherent when working with horses. As the veterans will only have one therapy session per week, it is expected that the burden associated with participation is relatively low compared to the possible benefit.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Veteran

Diagnosed with PTSD

Minimum of 18 years old

Therapy resistant, which is defined as "persisting PTSD diagnosis and lack of improvement in PTSD symptom severity following a full course of two individual trauma-focused therapies and treatment duration of at least 12 months."

## Exclusion criteria

Participates in other forms of therapy at the moment of participating in this study

Has a comorbid psychiatric or medical disorder that could be interfering with participation in the study

Is in a current legal claim procedure against the Ministry of Defence

Shows or has shown aggression towards other people and/or animals

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Treatment

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-04-2021
Enrollment:	64
Type:	Anticipated

## Ethics review

Approved WMO	
Date:	09-03-2021
Application type:	First submission
Review commission:	METC NedMec

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
CCMO	NL75890.041.20