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

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Ethical review Approved WMO

Status Pending

Health condition type Anxiety disorders and symptoms

Study type Observational non invasive

Summary

ID

NL-OMON49202

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 objective welfare parameters are the primary study parameters of this feasibility study. The following welfare parameters will be measured every week in veterans and horses;

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

Secondary outcome

Secundary study parameters of this feasibility study are the following 16 PTSD symptoms that will be measured using questionnaires;

- · 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 in dangerous
- Change in feeling that the nerve system is destroyed forever
- Participation and interest in activities
- Collaboration with other people
- Feeling positive
- Experiencing satisfaction
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- Experiencing happiness
- Finding a purpose / meaning in life
- Having a prospect for the future
- Sleep disturbances and insomnia
- Flashbacks / nightmares
- Stress levels

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, 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, in this feasibility study we want to know whether the effects that have been found in previous studies can also be measured in the human body using objectie 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. As a consequence, the responses of a therapy horse during a session might reveal something about the mental state of the veteran.

This feasibility study will therefore investigate objective welfare parameters

that could be relevant for investigating the effects of group therapy with horses on military veterans diagnosed with PTSD. This feasibility study hypothesizes that objective welfare parameters can be measured in veterans with PTSD symptoms during participation in the 12-week therapy program.

Study objective

The primary objective of this feasibility study is to measure objective welfare parameters (HRV, salivary cortisol and oxytocin and stress related behaviour) that are relevant for studying the effects of therapy with horses on veterans diagnosed with PTSD and to investigate if they correlate with subjective validated welfare parameters (questionnaires).

The secundary objective of this feasibility study is to investgate whether or not therapy with horses leads to an improvement in the quality of life of veterans that are diagnosed with PTSD. Quality of life will be measured using 16 objectives, which are related to PTSD symptoms.

Study design

This feasibility 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 Stichting Bio, which is located at Wekeromseweg 8 in Arnhem, 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 a joint lunch, the participants are going to work with the horses in pairs. At the end of the day there is time to reflect, share experiences and give feedback to each other. This session will be recorded using an audio recorder, so that the research team has the possibility to listen to the feedback and experiences of the participants afterwards and use these in the analysis of the resuts.

Heart rate measurements and saliva sampling will be done each week before, during and after working with the horses. Additionally, participants will be asked to take a saliva sample the evening before the session and bring it to the session the next day. Two out of the four questionnaires will be filled out each week after working with the horses, the other two questionnaires will be filled out once per month. 12 weeks after the last session the participants will be asked to come to Stichting Bio for a follow up measurement, in which they fill in the questionnaires for the last time.

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 feasibility study have experience with working with children with physical handicaps, which means that these horses 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

Public

Universiteit Utrecht

Yalelaan 2 Utrecht 3584 CM NL Scientific

Universiteit Utrecht

Yalelaan 2 Utrecht 3584 CM NL

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 individual trauma-focused therapy or repeated failed trials of individual trauma-focused therapy and treatment duration of at least 6 months."

Exclusion criteria

Participates in other forms of therapy
Is in a medical insurance procedure against the Ministry of Defence
Has shown aggression towards other people and/or animals
Is diagnosed with psychosis

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled Primary purpose: Treatment

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-09-2020

Enrollment: 8

Type: Anticipated

Ethics review

Approved WMO

Date: 19-08-2020

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 NL73047.041.20