Veterans with Post-traumatic Stress disorder Working dog Research (Vpwr) - The Interaction of Service Dogs and Military Veterans with Post-traumatic Stress Disorder

Published: 22-06-2018
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The aim of the study is to investigate the mechanisms behind and influence of the PTSS assistance dog on military veterans with PTSD.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Observational non invasive

Summary

ID

NL-OMON46486

Source
ToetsingOnline

Brief title
PTSD Service Dog Influence

Condition

- Anxiety disorders and symptoms

Synonym
Post-traumatic Stress Disorder PTSD

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Royal Canin Nederland B.V.,Stichting Karel Doorman Fonds;Royal Canin Nederland B.V.;aanvullende financiering nog in onderhandeling

Intervention

Keyword: Assistance, Dog, PTSD, Veteran

Outcome measures

Primary outcome

Cortisol level in saliva

Cortisol level in hair

PTSS questionnaire score

Quality of life questionnaire

Sleep quality questionnaire

Man dog attachment questionnaire

Heartbeat

Blood pressure

3D Activity

GPS activity

Secondary outcome

N.A.

Study description

Background summary

For some time there has been evidence availible that underlines the positive influence of assistance dogs for military veterans with PTSD on the control and

reduction of PTSD symptoms. This evidence is composed of a combination of self-reflection by veterans, subjective research into the well-being of people, and case-reports based on observations. As a result, this evidence is only based on subjective observation of the relationship between veterans and PTSS assistance dogs, which makes it weak and tending towards face validity.

The lack of evidence about the influence of PTSS assistance dogs on the control and reduction of PTSD symptoms means that at present no sensible statements can be made about the exact manner in which the above-mentioned experiences and observations may have come about. For example, it is unclear whether the specific selection and training of individual PTSS assistance dogs contributes to their perceived effectiveness. Research into the interaction between humans and pets, in particular dogs, has already shown that positive interaction between the two can bring about an experience of positive emotions. This effect is undoubtedly also present between military veterans and PTSS assistance dogs, which makes it doubtful to what extent specialized training has contributed to observed results. In addition, due to the circulation of numerous success stories nowadays, it can not be excluded that veterans with PTSD who come into the possession of a PTSS service dog, automatically assess their own well-being better / higher than before due to placebo effect. The assesment of improved welfare an therefore not directly be attributed to the dog, let alone his specialized training.

Because of all the above, it is currently very uncertain how the PTSS assistance dog affects those who are supported by the dog and to what extent the improvement in veterans can actually be attributed to the dog. It is therefore important that thorough and objective research is conducted into the efficacy, employability and general influence of assistant dogs for military veterans with PTSD, so that insights based on empirical evidence can be generated, which can help develop this form of therapy support. .

Study objective

The aim of the study is to investigate the mechanisms behind and influence of the PTSS assistance dog on military veterans with PTSD.

Study design

This study consists of several measurement moments. The number of measurement moments differs per group of participants (between 1 and 6 moments). In the case of multiple measurement moments, the minimum interim period is 2 months. The maximum time between the 1st and 6th measuring moments is 2 years.

A single measurement moment consists of nine days. On the 1st and 9th day,

participants are visited by the researchers. The 1st visit takes about 66 minutes, the second 30 minutes. In the 7 days between visits, participants are asked to take different samples themselves and to keep records. This takes 24 minutes a day the first two days and less than 5 minutes on the remaining days. The total time load is estimated at 199 minutes per measurement moment divided over 9 days.

For each measurement moment participants will be asked to participate in multiple measurements: First of all, participants will be asked to fill in six questionnaires per measurement moment. These will be spread over the 9 days that take a measurement moment. Participants are also asked to participate in 3 saliva measurements around the first 2 of the aforementioned questionnaires. These will be used for the determination of oxytocin levels in both the participant and his (assistance) dog in response to the first 2 questionnaires. The first measurement takes place just before the 1st questionnaire, the 2nd immediately after completion of the 2nd questionnaire, and the 3rd 30 minutes after completion. Samples are taken with a swap which must be kept in the mouth for 1 minute to passively absorb saliva. Because of potential sample contamination, participants are asked to eat or drink nothing but flat water from 30 minutes before and during these measurements.

Furthermore, participants will be asked to record their own GPS data for 7-day, using a mobile app.

Participants are asked to take 5 saliva samples per day of their own and their assistance dogs (if applicable) for 2 days. This gives a total of 10 samples for humans and 10 for dogs. Samples are taken with a swap which must be kept in the mouth for 1 minute to passively absorb saliva.Because of potential sample contamination, participants are asked to eat or drink nothing but flat water from 30 minutes before and during these measurements.

Some participants will be asked to wear a physiological measuring instrument for the period of 48 hours. This instrument has about the size of a watch and registers heart rate, blood pressure, and activity while being worn.

At the end of the study, a (small) hair sample from each subject is asked for cortisol analysis.

Data as described above will be encripted by assigning a code to each subject. The key for this code is known only to the researchers. Data from 1 subject will remain linked under this code.

Study burden and risks

Possible positive diagnosis for PTSD by completing the PTSS questionnaire while this diagnosis was not yet known to the subject. The researchers maintain the option that unexpected diagnoses of PTSD are not likely to occur during the

study.

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

Shared inclusion criteria between all participating subjects are, all subjects must be military or ex-military personnel, at least 18 years of age or older, of mixed sex, and capable to give written consent for participation. More specific inclusion criteria differ between subject groups, and concern specific lifestyle details like the current presence of a PTSD service dog for an individual.

Exclusion criteria

Exclusion criteria for all subjects are, non-military personnel, younger than 18 years of age, not mentally capable of giving written consent, and aggressive behaviour.

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:	Recruitment stopped
Start date (anticipated):	03-12-2018
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO

Date:	22-06-2018
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	NL64117.041.18

Study results

Date completed:	31-08-2021
Actual enrolment:	65