Veterans with Post-traumatic Stress Disorder Working dog Research (V-PWR) 2.0 - The Influence of Service Dogs on Military Veterans with Post-traumatic Stress Disorder and their Families

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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-OMON53269

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: Stichting Karel Doorman Fonds en een anoniem fonds

Intervention

Keyword: Dog, Family, PTSD, Veteran

Outcome measures

Primary outcome

PTSD questionnaire

Secondary outcome

Cortisol level in saliva

Cortisol level in hair

Oxytocin level in saliva

Quality of life questionnaire

Sleep quality questionnaire

Family system questionnaire

Human dog attachment questionnaire

Relationship satisfaction questionnaire

Children mental health questionnaire

Children parent interaction questionnaire

Children dog attachment questionnaire

Service dog retirement interviews

Heartrate

Heart rate variability

Activity

Telomerlength in buccal membrane of service dogs and companion dogs

Study description

Background summary

In a literature review van Houtert et al. (2018) noted that much of the presented evidence of post-traumatic stress disorder (PTSD) service dog effectiveness was either based on anecdotal documentation, self-reflection by subjects, or indirect study of the topic. Therefore, van Houtert et al. (2022) evaluated and used existing techniques to study the effects of PSDs on military veterans. The results of questionnaires were compared to objective parameters, including salivary cortisol samples, heartrate measurements and activity levels. Four subject groups were investigated; veterans with PTSD and a service dog, veterans with PTSD and a companion dog, veterans with PTSD without a dog and a control group of veterans without PTSD. Results of this study were promising, as veterans with PTSD who had a service dog showed less PTSD related symptoms, better wellbeing and better sleep quality compared to those with a companion dog and those without a dog. However, no significant results were found for the objective parameters, aside from the fact that veterans with a service dog tended to walk more than individuals in the control group. Van Houtert et al. (2022) concluded that the use of objective measurement methods to investigate PSD effectiveness needs more research. Furthermore, during the study by van Houtert et al. (2022), additional questions were raised, which we aim to answer in the current study.

Firstly, existing research suggests that the partner and children of a veteran are also negatively affected by the veteran*s PTSD. To date, literature on the effects of PTSD service dogs (PSDs) has almost solely focused on the effect of PSDs on the veteran, rather than on the family as a whole. The few studies that have investigated the effects of PSDs on the families of veterans provide promising results, but these results are again based on anecdotal documentation or self-reflection. Therefore, this study would like to investigate the influence of PSDs on the partner and children of military veterans with PTSD, using both subjective and objective measurements.

Additionally, the current study will add additional objective parameters, including salivary oxytocin. Oxytocin is a hormone and neurotransmitter that manages key aspects of the reproductive system of males and females, including childbirth. Besides, oxytocin is known for various health benefits, including reduced stress and improved cardiovascular function. The hormone is also increasingly recognized to have a role in human-dog interactions, and it is suggested that PSDs enhance oxytocin levels in veterans with PTSD. Therefore, we want to investigate the effect of interactions between veterans with PTSD

and their service dog on oxytocin levels in both, as an increase in oxytocin levels could promote human-dog bonding as well as the overall health of the veteran.

This study will also look into the effects of service dogs on heart rate variability (HRV) of the veterans. Existing research shows that humans with PTSD have lower HRV at baseline and throughout different conditions than individuals without PTSD. Therefore, this study aims to investigate whether PSDs increase HRV in veterans with PTSD.

Finally, this study aims to investigate the effect of retirement of the service dog on the veterans, as this is something that all veterans with a service dog will have to deal with at some point. Although retirement of the service dog is inevitable for all humans with a service animal, research on this particular topic is scarce. Ng and Fine (2019) recommended studies to explore the emotional and practical experience when preparing for and adjusting to retirement of their service animal, which is what this study aims to investigate.

Study objective

The aim of this study is to identify whether the availability of a PSD for military veterans with PTSD coincides with clinically significant changes in wellbeing, behaviour and functioning in veterans and their families compared to veterans with PTSD and their families who are on the waitlist for a PSD.

Study design

This study consists of several measurement moments that take place every six months during three years.

A single measurement moment consists of seven days. On the 1st and 7th day, participants are visited by the researchers. For veterans with a service dog the 1st visit takes about 76 minutes, the second 55 minutes. The total time load for veterans with a service dog is estimated at 186 minutes per measurement moment. For veterans in the control group the 1st visit takes about 66 minutes, the second 40 minutes. The total time load for veterans in the control group is estimated at 141 minutes per measurement moment. For partners of the veterans the 1st visit takes about 56 minutes, the second 40 minutes. The total time load for partners is estimated at 131 minutes per measurement moment. For children of subjects the 1st visit takes about 46 minutes, the second visist 25 minutes. The total time load for children is estimated at 91 minutes per measurement moment.
On the 5th and 6th day of the measurement moment, participants will be asked to conduct measurements themselves. This is expected to take around 20 minutes per day.

For each measurement moment participants will be asked to participate in multiple measurements: First of all, veterans with a service dog will be asked to fill in five (participants without partner or children), six (participants with partner or children) or seven (participants with partner and children) questionnaires per measurement moment. Veterans on the waitlist for a service dog will be asked to fill in three (participants without partner or children), four (participants with partner or children) or five (participants with partner and children) questionnaires per measurement moment. The partner of each veteran subject is asked to fill in three (participants without children) or four (participants with children) questionnaires per measurement moment. Children of subjects are asked to fill in three questionnaires. All questionnaires will be spread over the two house visits by the researcher.

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

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

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

Aside from the measurements during the measurement moment, veteran participants will be asked to come to an external location once to participate in an "interaction day". This is expected to take one morning or one afternoon. The external location is yet to be decided. During this interaction day, participants will be asked to perform an assignment with their service dog. Saliva samples will be taken from both the veteran and the service dog before and after completing the assignment. These saliva samples will be used to assess levels of the hormones cortisol and oxytocin.

Aside from the measurements during the measurement moment, participants whose service dog will retire during this study will be asked to participate in at least one semi-structured interview, in order to investigate the effects of service dog retirement. This interview is assumed to take around 30 minutes, and contains questions about the emotional and practical consequences of service dog retirement for the veteran. Depending on the willingness of subjects to participate, subjects will be asked to participate in a second interview a few months after service dog retirement, in order to investigate the effects of service dog retirement on the longer term.

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.

Study burden and risks

The researchers are not aware of any risks associated with participation in this study.

The estimated time load for participating veterans with a service dog is 186 minutes per measurement moment. The estimated time load for participating veterans in the control group is 141 minutes per measurement moment. Veterans participate in a maximum of 6 measurement moments, which take place every six months during three years.

Aside from the measurement moments, veteran participants will be asked to come to an external location once to participate in an "interaction day". This is expected to take one morning or one afternoon. Veterans whose service dog will retire during this study will be asked to participate in at least one semi-structured interview that will take around 30 minutes. Depending on willingness of subjects to participate, subjects will be asked to participate in a second interview a few months after service dog retirement, which will also take around 30 minutes.

For partners of the veterans the estimated time load is 131 minutes per measurement moment. For children of the veterans the estimated time load is 91 minutes per measurement moment. Partners and children of the veterans will also participate in a maximum of 6 measurement moments, which take place every six months during three years.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Shared inclusion criteria between all participating veteran subjects are; all subjects must be military or ex-military personnel, at least 18 years of age, both men and women, capable of giving written consent for participation, and be in possession of a service dog from 'Stichting Hulphond Nederland' or 'KNGF' or be on the waitlist to receive a service dog from 'KNGF'.
For partners of veterans the inclusion criteria are at least 18 years of age, currently in a relationship with military or ex-military personnel, who is in possession of a service dog from Stichting Hulphond Nederland or KNGF or on the waitlist for a PTSD service dog from KNGF.
For children the inclusion criteria are at least 4 years of age, both boys and girls, having at least one parent that is military or ex-military personnel and that is in possession of a service dog from Stichting Hulphond Nederland or KNGF or on the waiting list to receive a service dog, and living with that parent for at least one day per week. For participating children the parents must be capable of giving written consent for participation.

Exclusion criteria

Exclusion criteria for all adult subjects are, younger than 18 years of age, not mentally capable of giving written consent, and pregnancy during the study.
Exclusion criteria for children of subjects are parents not being mentally capable of giving written consent.

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):	01-08-2023
Enrollment:	130
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	02-08-2023
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	30-04-2024
Application type:	Amendment
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	NL84604.041.23