Attention Control Training (ACT) in PTSD patients: a randomized controlled trial.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29598

Source
Nationaal Trial Register

Brief title
TBA

Health condition

PTSD

Sponsors and support

Primary sponsor: None.
Source(s) of monetary or material Support: None.

Intervention

Outcome measures

Primary outcome

The most important primary research variable is the decrease in PTSD symptomatology between the experimental group and the control group. We use the PCL-5 to measure this.

Secondary outcome

The secondary research variables are the differences in general well-being; degree of aggression and quality of life between the experimental group and the control group. We use the PHQ-4, Buss-Perry and ORS questionnaires for this.

Study description

Background summary

During a traumatic experience there are two ways of information processing:
1) Conceptual processing
2) Data-driven processing (data-driven processing)

Ad 1) Conceptual processing means that the meaning of the traumatic experience is processed in an organized way and that the information is placed in a context by making connections with existing concepts, knowledge and views within the person.
Ad 2) Data-driven processing means that primarily the sensory aspects are processed, such as sensory, visual and auditory information, without the information having a clear context and being integrated into the autobiographical memory. When the information in the representation of the trauma in the memory consists mainly of sensory information and relatively less conceptual processing has taken place, the memory, when activated, triggers a sense of re-experience. When the traumatic experience leads tops views that are very threatening (eg the world is dangerous) this complicates the integration of the trauma information into the autobiographical memory. The result is that the memory can be activated quickly and automatically by internal and external stimuli and is experienced in the here-and-now (also known as flash-backs).

For example, trauma victims more easily remember parts of the trauma that matches their interpretations of what happened. Corrective information is not noticed or processed as quickly and this creates a vicious circle.
In accordance with the vicious circle of distortions in the memory and the interpretation, people with a PTSD will also more quickly perceive trauma-related stimuli from the environment (perceptual priming), also known as attention distortion. For example, someone who has ever experienced a dangerous fire will be more likely to see an upcoming fire truck than someone without such an experience.

Against this light, I want to investigate whether an ACT, prior to the TAU (EMDR or imaginary exposure), leads to a better outcome.

Study objective

Does a Attention Control Training in patients in the experimental group with a PTSD prior to the TAU lead to a better outcome than in patients in the control group with a PTSD who have received a sham (fake) training prior to the TAU ? This is also the primary outcome measure to be measured by means of the PCL-5 (degree of PTSD symptomatology).

The secondary outcome measure is general well-being; measure aggression and quality of life through the PHQ-4 (health questionnaire); Buss-Perry aggression questionnaire and ORS quality of life questionnaire.

Study design

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Intervention

1) One group receives an ACT training: 12 sessions once a day for 5 minutes and another group receives a sham training: 12 sessions once a day for 5 minutes.
2) After the training, both groups receive a treatment as usual (TAU) consisting of EMDR or imaginary exposure (6 sessions)

Contacts

Public
GGz Praktijk
Bas Schrijner

06-24238189
Scientific
GGz Praktijk
Bas Schrijner

06-24238189

Eligibility criteria

Inclusion criteria

Participants are admitted if PTSD has been determined in the intake with the help of the PCL-5 and LEC-5 and clinical judgment according to the DSM-5.

Exclusion criteria

The exclusion criteria are:
1) psychotic or bipolar disorder
2) nonfluent Dutch

3) inability to use a computer keyboard
4) current psychotherapy
5) use of psychotropic medication that started within the past year. Participants will be removed from the study if their medication has to be changed during the trial. They will be admitted if they have been taking a stable dose of medication for at least 1 year.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2019
Enrollment:	66
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
no idea

Ethics review

Positive opinion

Date:	10-07-2019
Application type:	First submission

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
NTR-new	NL7936
Other	METC AMC : METC65710

Study results

Summary results
none