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

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Main outcome is the stronger reduction in PTSD symptoms in the ACT+EMDR condition compared to the Control+EMDR condition.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON55472

Source
ToetsingOnline

Brief title
ACT-IPP

Condition

- Other condition

Synonym
trauma-related disorder(s); PTSD

Health condition

trauma-en stressorgerelateerde stoornis (PTSS)

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Geen financiering.

Intervention

Keyword: Attention, Control, EMDR, PTSD

Outcome measures

Primary outcome

The most important primary research variable is the (differential) decrease in PTSD symptomatology between the experimental group and the control group from baseline (T0) to post-EMDR (T2). We use the PCL-5 to measure this. The 20 items of the PCL-5 can be answered on a 5-point scale from *Not at all* (0) to *Extremely much* (4). Completing the PCL-5 takes about 5-10 minutes. The interpretation of the PCL-5 should be made by a clinician.

PCL-5 scores demonstrated similarly strong reliability and validity. Overall, results indicate that the PCL-5 is a psychometrically sound measure of PTSD symptoms (Blevins & Weathers & Davis & Witte & Domino, 2015).

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-9, AGQ and ORS questionnaires to measure this.

The PHQ-9 questionnaire consists of 9 questions about the severity of depressive complaints based on the DSM IV criteria, with a maximum score of 27 points. The AGQ is a 29-item, four-factor instrument that measures physical aggression, verbal aggression, anger, and hostility. The ORS is a simple, four-item session-by-session measure designed to assess areas of life functioning known to change as a result of therapeutic intervention. These include: symptom distress, interpersonal well-being, social role, and overall

well-being. The ORS translates these four dimensions of functioning into four

visual analogue scales which are 10cm lines, with instructions to place a mark

on each line with low estimate to the left and high to the right.

Study description

Background summary

PTSD is a highly prevalent health issue, with serious consequences in terms of morbidity and mortality, economic costs, and social problems.
There are good and easily applicable treatment options for treating PTSD and other trauma-related complaints. Recent Dutch research shows that PTSD can be treated safely and effectively with EMDR and prolonged imaginary exposure (Berg et al., 2015). Although EMDR and PE are the first choice in the treatment of PTSD, there is still room for improvement. After treatment many patients remain symptomatic (Schnurr et al., 2007). In addition, the dropout percentages are significant and range between 20 and 35% (Schnurr et al., 2015 & Steenkamp, M., Litz, B., Hoge, C.W., & Marmar, C., 2014). Attention bias may play a role in this and it is therefore interesting to pay attention to this.
During a traumatic experience there are two ways of information processing (Ehlers & Clark, 2000): Conceptual processing and data-driven processing (data-driven processing).
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.
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 (e.g. 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.
Vermetten (2009) indicates that the prefrontal cortex is an important mechanism behind both the consolidation and extinction of anxiety. According to Vermetten, conditioned emotional responses do not extinguish from repeated exposure to conditioned stimuli without the aversive stimulus.
Woud & Krans (2013) indicate that it is of clinical importance to take these cognitive distortions in treatment seriously as the subject of treatment. According to them, these distortions can be changed using cognitive bias modification techniques.
There are indications that the attention system of anxious individuals has a distortion of attention in the direction of threat. This is not the case with non-anxious individuals (Bar-Haim et al., 2007). Research by Badura-Brack et al. (2015) shows in two randomized control trials that an attention control training (ACT) provides significantly better symptom reduction than attention bias modification (ABM) in PTSD patients. In addition, they found that an ACT and not ABM significantly reduces attention distortion. They conclude that with a reduction in attention bias a significant decrease in trauma-related problems occurs.

Taking these results into account, it is interesting to see what the effects of EMDR are on PTSD symptomatology after this ACT training. These studies do not answer that. We hope to be able to answer that with this research. Therefore we think it is important to investigate whether an ACT compared to a placebo intervention, prior to the EMDR treatment, leads to a better outcome.

Study objective

Main outcome is the stronger reduction in PTSD symptoms in the ACT+EMDR condition compared to the Control+EMDR condition.

Study design

A double-blind randomized placebo-controlled trial will be conducted.
This is a double-blind randomized controlled trial with an experimental and control group.
The research will be chronologically in time as follows:
1) A standard intake procedure will take place by administering the PCL-5; LEC-5; PHQ-9; AGQ and ORS (T0) and the PTSD will be diagnosed by the Clinician-Administered PTSD scale for DSM-5.
2) The person concerned and diagnosed with PTSD is asked if he wants to participate in the investigation.
3) If so, randomization takes place. If not, the person will receive a treatment as usual.

4) The person concerned will then undergo an ACT or ACT-sham training of 12 sessions (2 sessions 5 minutes per day, so 6 days in total).
5) Then we have through the PCL-5 again a measuring moment (T1).
6) Afterwards, each test subject will undergo 6 sessions EMDR.
7) Finally, after these 6 sessions, we have another measuring moment (T2) by taking the PCL-5; PHQ-9; AGQ and ORS.

Intervention

ACT training involves a simple computerized performance task, that is non-invasive, requires little cognitive effort, and does not affect the personal integrity of participants.
Performing reaction time tasks on the computer (ACT training), whereby simple responses must be given. During the task, distractor stimuli are shown with an emotional charge. The stimuli are not extreme, but consist of faces with a neutral or angry expression. The tasks are performed as training in 12 sessions of 5 minutes each 2 times per day, so 6 days in total.
Attention Control Training, or De-salience Training, task:
Each session of the training task consisted of a block of 120 trials of a dot-probe task. Trials began with a white fixation cross, onscreen for 200, 300, or 400 ms (with equal probabilities). On every trial a neutral and an angry face were then presented as cues, one above and one below a fixation cross, for 400 ms. The facial stimuli were selected from a subset of 11 faces from the BESST (Thoma et al., 2013). Following the cue period, a probe stimulus appeared at one of the locations (above or below fixation) at random. Probes were left- or right-arrows (<< or >>), requiring a left- versus right-hand button press response. On the other location, a distractor stimulus with similar visual features was presented (\\ or //), to the aim of making it more difficult to recognize the probe without actually shifting attention to its location. The location of the probe stimulus was random and had no relationship to the locations of the angry and neutral faces presented as cue: This was intended to train the participants to learn that the cues were irrelevant.
In the Neutral control condition, only neutral faces were presented, removing the primary negative emotional component of stimuli.

Description ACT training see heading E4.

Study burden and risks

With regard to risks associated with participation, it is highly unlikely that participants will suffer any negative consequences of the ACT training or placebo-training. ACT training involves a simple computerized performance task, that is non-invasive, requires little cognitive effort, and does not affect the personal integrity of participants.
The burden consists of filling in standard questionnaires about mental health and PTSD (PCL-5; LEC-5; PHQ-9; AGQ and ORS). Secondly, from performing reaction

time tasks on the computer (ACT training), where simple responses must be given. During the task, distractor stimuli are shown with an emotional charge. The stimuli are not extreme, but consist of faces with a neutral or angry expression. As mentioned earlier, this training has been used successfully in patient populations without serious side effects. The questionnaires are not intrusive and are comparable to questionnaires that are also completed in the context of the treatment. In total, completing the questionnaires takes around 10 minutes.
The study tests an experimental intervention from which patients could hypothetically benefit, if results provide sufficient evidence to incorporate the intervention in practice. The training is hypothesized to improve patients' ability to self-regulate their cognition and emotion and to improve how well they profit from therapy. The training would be very cost-effective. The potential benefits of the study are thus significant, against only minimal costs/risks.

Contacts

Public
Universiteit Utrecht

Heidelberglaan 8
Utrecht. 3584 CS
NL
Scientific
Universiteit Utrecht

Heidelberglaan 8
Utrecht. 3584 CS
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Participants are admitted if PTSD has been determined in the intake with the help of the PCL-5 and LEC-5 and CAPS.

Exclusion criteria

The exclusion criteria are:
1) psychotic or bipolar disorder
2) nonfluent Dutch
3) patient does not have a computer
4) no internet access at home
5) inability to use a computer keyboard
6) current psychotherapy
7) 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:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-05-2021
Enrollment:	66

Type:	Actual

Ethics review

Approved WMO Date:	18-05-2021
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	NL65710.041.20
Other	NTR NL7936