Eye Movement Desensitisation and Reprocessing therapie (no) more Pressure. Does wearing a pressure vest reduce anxiety and dissociation during EMDR?

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2. OBJECTIVES2.1 Primary Objective Do clients experience less anxiety and less dissociation when wearing a pressure vest during EMDR sessions than when they do not wear a pressure vest during EMDR sessions?2.2 Secondary Objective(s) Do clients...

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

Summary

ID

NL-OMON53783

Source
ToetsingOnline

Brief title
EMDR (no) more Pressure.

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym
complex post traumatic stress disorder

Health condition

psychische stoornissen trauma/PTSS complex met angst, emotieregulatieproblemen en/of

dissociatie

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Westelijk Noord-Brabant (Halsteren)
Source(s) of monetary or material Support: Ministerie van OC&W,De instelling (GGZ WNB) zelf.

Intervention

Keyword: anxiety, dissociation, EMDR, pressurevest

Outcome measures

Primary outcome

6 METHODS

6.1 Study parameters/endpoints

6.1.1 Main study parameter/endpoint

The primary outcome measures are anxiety and dissociation, measured after each session on a 10-point scale. The research question is answered by calculating differences in anxiety and dissociation between sessions with and without pressure vest.

Secondary outcome

6.1.2. Secondary study parameters/endpoints (if applicable)

The average number of minutes needed to reach SUD=0 with/without pressure vest. The secondary research question is answered by calculating differences in the mean number of minutes needed to arrive at SUD=0 between sessions with and without pressure vest.

6.1.3 Other study parameters (if applicable)

Not applicable

Study description

Background summary

1. INTRODUCTION AND RATIONALE

The Netherlands has about 400,000 people with PTSD every year, according to the National Health Care Institute (PTSD Improvement Report, 2020). Only 10 to 35% of people with PTSD appear to seek help. Trauma-oriented treatment also appears to have a high incidence of dropout, on average about 16% (Lewis et al., 2020). However, this differs greatly between client populations. Veterans, for example, show a high rate of 68% dropout (Schok, 2013). Therapies that focus on the here-and-now appear to show less dropout. Other researchers report a 40% dropout rate in cognitive processing therapies for trauma (Alpert et al., 2019). Focus on the here-and-now, as well as the fact that only 10 to 35% of people with PTSD seek help, could indicate people's fear of dealing with their trauma. This seems consistent with research on trauma-related cognitions. (Van Emmerik, 2007; Merker et al., 2020). The concept of 'window-of-tolerance', which is often used in the trauma world, also comes in handy here (Siegel, 1999). This theory assumes that processing requires staying within an optimal voltage window. People with PTSD may have a fear of getting out of their window-of-tolerance, even during trauma treatment. Deep pressure, such as is obtained, among other things, while wearing a pressure vest, is known to have a calming and concentration-enhancing effect. (e.g. Grandin, 1992; Brazelton, 1990; Gunzenhauser, 1990; Alder, 2020; Minoura et al., 2020) This study wants to add the calming and concentration-enhancing effect of the pressure vest to an already proven effective trauma treatment (EMDR) and investigate whether this reduces participants experienced fear and less dissociation during the EMDR sessions in which they wear the pressure vest than in the EMDR sessions in which they do not wear the pressure vest. A second research question is whether the mean number of minutes needed to reach a subjective units of distress (SUD) score of 0 during the EMDR treatment is smaller in the sessions with a pressure vest than in the sessions without a pressure vest.

Study objective

2. OBJECTIVES

2.1 Primary Objective
Do clients experience less anxiety and less dissociation when wearing a

pressure vest during EMDR sessions than when they do not wear a pressure vest during EMDR sessions?

2.2 Secondary Objective(s)
Do clients experience a faster SUD drop in the vested sessions compared to the no vest sessions?

Study design

3. SINGLE CASE EXPERIMENTAL DESIGN Quantitative research in the form of a Single Case Experimental Design (SCED). It concerns an alternating treatment design (ATD), of the SCEDs most suitable for randomization (N-of-1 RCT). Ambulatory adult SGGZ clients aged 18 to 65 come to the Change-oriented and Young Adults departments of GGZ WNB. Clients with at least an IQ of 85 who come for treatment of more than one trauma (multiple trauma), who are not acutely psychotic and where no addiction is paramount, will be asked whether they want to participate in the study. • As soon as clients agree to the examination, a pre-measurement is taken (for measuring instruments, see appendices F1). This takes about 40 to 70 minutes. • After this, the treatment starts, which consists of several sessions of EMDR (standard of care PTSD: 6 to 12 sessions). Clients will receive treatment until they are 'finished' with their PTSD treatment. This is also for ethical reasons. • For every two sessions, a randomization program (ATD) determines which of those two sessions the pressure vest is not worn (condition A) or whether is worn (condition B). This randomization is repeated for every two sessions, resulting in the pressure vest being worn as often as not. This creates many possible sequences of alternating treatment with the pressure vest. For randomisation, use is made of the randomisation program developed by KU Leuven (see chapter 6, methods; in particular paragraph 6.2). The pressure vest is professionally measured and there is a separate instruction, so that the way of wearing is comparable between different participants and as intended according to the manufacturer/supplier and according to CE approval. (Size S = 15/20 pumps; size M = 20/25 pumps; size L = 25/30 pumps. See also Appendix C of the 'subject information', form E1.) • During each session, some scores are also taken, such as the SUD, according to EMDR protocol. But also perceived fear and perceived dissociation are scored on a scale of 0 to 10 at the end of each session. • After the full EMDR treatment, but maximum after 12 sessions, a post-test is performed on the client (see appendices F1 for the measuring instruments). This measurement also takes 40 to 70 minutes. In total, this concerns a pre-measurement, in which, in particular, the assessment also takes place and the target group is determined, as well as the seriousness of complaints. A post-test for this seriousness of complaints is also performed after the treatment. ========== 6.3 Study procedures
6.3.1 Measurement(s) to be administered each EMDR session At the end of each session, two scores are requested: - A score on a scale of 0 to 10 for the fear experienced during the session, where 0 = no fear and 10 = maximum experienced

fear. - A score on a scale of 0 to 10 for the degree of dissociation experienced during the session. Again, 0=no experienced dissociation and 10=constantly / throughout the session experienced dissociation. (minimum 6 sessions / measurements of 5 minutes) The SUD (Subjective Units of Distress) score during the EMDR. The SUD score is requested at the start of each session according to EMDR protocol for the target concerned and also according to EMDR protocol regularly during the session. This continues until the SUD=0. When the SUD has dropped to 0 during a session, the time during that session is noted. This is so that the total time required to determine a SUD decrease or the number of points SUD decrease within a certain time can be determined. In any case, at the end of each session, the SUD of a target that has been worked on is determined in accordance with the EMDR protocol. >>> SUD determination is therefore no extra burden for participants, because it is part of the regular EMDR protocol. 6.3.2 Instruments included in the pre- and post-measurement: • To be able to be included in the study and to determine that there is PTSD: CAPS-5 (Clinical Interview PTSD) • LEC-5 (Life Events Checklist for DSM-5) a self-assessment questionnaire for the inventory of major and/or stressful events. Targets for EMDR can also be determined using this. These questionnaires are normally administered to every registered client with trauma complaints, so this is also no extra burden for participants. (10 minutes) • Dissociative reactions can be part of criterion B of PTSD according to the DSM-5, as can physiological reactions. These are measured with: • DES (Dissociative Experience Scale) 28 questions to more specifically map the degree of dissociative complaints. (approx. 10 minutes) • SBC (Scale of Body Connection) 20 questions about the degree of connection that the participant experiences with his/her body and to map out any somatic dissociative complaints. (5-10 minutes) DSM-5 screeners to visualize comorbidity (and to be able to say something about the complexity of both groups): • SCID-5-SV (Structured Clinical Interview DSM-5 Syndrome Disorders Questionnaire - screener) to gain insight into other psychological complaints, which regularly accompany trauma complaints, such as anxiety, depression, panic, concentration problems, etcetera. (10-20 minutes) • SCID-5-PV (Structured Clinical Interview DSM-5 Personality Questionnaire - screener) to map out any degree of personality problems. (20 minutes) These screeners are normally also regularly indicated and administered as ROM, certainly in the SGGZ population. Therefore it is not an additional burden. In doing so, the researcher opts practically for the above-mentioned questionnaires and screeners, because they can all be prepared within the ROM system of the GGZ WNB and can therefore easily be completed digitally by participants. In addition, they are scored automatically. Licenses are available. Whenever possible, the shortest variant of questionnaires was chosen in order to burden participants as little as possible with questionnaires. In that case, participants can choose to fill in the questionnaires somewhat divided over time (within a time frame of one week). In total, filling in the questionnaires takes the participants about 40 to 70 minutes per measurement (before and after measurement). During the post-test, the test subjects will also be asked: *How did you experience the pressure vest?* This gives subjects the opportunity to briefly tell their own

story. Information obtained from this will be analyzed qualitatively. 6.3.3 Safety of the Squease Pressure Vest During the development of the Squease deep pressure vest, the manufacturer/supplier had frequent contact with the MMC in Eindhoven. The Quality & Safety department and the Pulmonary Medicine department advised them during the development. The pulmonologists indicated that applying pressure to the upper body for a long time with the pressure vest cannot cause any damage. The pressure vest puts pressure on the rib cage and only activates the deep layers of the skin. In case of doubt, the supplier always advises to consult with a concerned doctor or healthcare professional. The pressure vest is approved as a 'medical device, type 1'. (See Appendix D4.) Effect of the pressure vest on breathing The vest falls just to / above the navel so the abdomen is free for abdominal breathing. The pressure vest makes you more aware of breathing due to the pressure on the upper body. Because the air can be distributed differently in the air chambers, the chest can still expand well when you breathe in the chest. The sizes small, medium and large also have elastic bands in the back, which do not hinder the rib expansion for breathing. Because the vest falls above the navel, it is not a problem in case of pregnancy, at most extra Velcro parts will be needed further in the pregnancy. 6.3.4 Medical Indications Squea

Intervention

5. TREATMENT OF SUBJECTS
The participants/clients are all diagnosed with PTSD and suffer from multiple trauma (several traumatic experiences in their lives). For this they are treated with EMDR for at least 6 weeks, once a week for an hour.

5.1. Investigational product/treatment
A pressure vest is a kind of body warmer, which can be brought to light pressure with a hand pump. The vest already has the intended effect when it is inflated 'firmly but comfortably'. It depends on the size of the pressure vest, how many times it needs to be pumped. (See Appendix D in Subject Information -E1- Pressure Vest Instructions for Use.)

5.2. Use of co-intervention
During the EMDR treatment it is not a problem if clients also follow another treatment. Because the scores are compared between EMDR sessions within the person, and it is determined at random which sessions the patient does / does not wear a pressure vest, each participant is his own control. This controls the possible effect of external factors such as additional treatment.

Study burden and risks

All participants receive evidence-based trauma treatment. The pressure vest is added, there are no negative experiences with it from the literature. It is a registered class I medical device and is authorized for use as such (in 2012).

In addition, participants complete questionnaires before and after the treatment. The questionnaires can be experienced as burdensome. Today, however, questionnaires (ROM) are used as standard. Incidentally, EMDR treatment can also be experienced as burdensome. This is why so many failures are reported in trauma treatment. (See also rationale.)

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Ambulant patient has multiple traumata, age between 18 and 65, IQ above 85.

Exclusion criteria

Patient is not psychotic at the moment of treatment, and patient does not have an addiction that neads immidiate attention/treatment. Patient does not use Port-a-Cath, Mic-Key, or drain, and has no major skindisseases. Patient is not pregnant during the study.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-09-2023
Enrollment:	12
Type:	Actual

Medical products/devices used

Generic name:	pressure vest
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	29-06-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL81802.029.22