Self-Esteem Treatment in Anxiety - positive versus negative memory representations

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We want to answer the following research questions:- Which of the mentioned treatment approaches is more effective for improving self-esteem?- Do both approaches have additive value (does a patient benefit more after receiving both treatments, in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON40665

Source
ToetsingOnline

Brief title
SETA trial

Condition

- Anxiety disorders and symptoms

Synonym
Anxiety Disorders | Anxiety symptoms

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anxiety, Cognitive Behavioral Therapy, Memory representations, Self-esteem

Outcome measures

Primary outcome

Self-esteem. This will first of all be measured using the Rosenberg Self-esteem Scale. This is a frequently used scale within self-esteem studies all over the world (Schmitt & Allik, 2005), and the revised version has a somewhat better construct validity than the original version, although both are equally reliable (Wongpakaran, Tinakon, Wongpakaran, & Nahathai, 2012). In the Netherlands, an average score of 31.6 has been found (SD=4.5) within a healthy population, and we will apply the cut-off of 26 for inclusion in our study (one standard deviation below average) (Schmitt & Allik, 2005). Also, we will use the Self-Esteem Rating Scale - Short Form (SERS-SF), as this instrument measures negative as well as positive subdomains of self-esteem in a valid way (Lecomte, Corbière, & Laisné, 2006).

Secondary outcome

Anxiety symptoms. For this we will use the Dutch version of the Spielberger State-Trait Anxiety Inventory (STAI). It consists of two subscales with each twenty 4-option items. It measures anxiety as a condition as well as anxiety as a trait of personality. The STAI has been validated, for example in the light of DSM-IV anxiety disorder symptoms (Okun, Stein, Bauman, & Silver, 1996). A cut-off score of 39 can be used for the state part of the scale, indicating psychopathology (Julian, 2011).

General psychopathology. For this, the Brief Symptom Inventory (BSI) will be used. This is a short version of the SCL-90. It is a self-administered scale that measures somatic and psychological symptoms for screening general psychopathology. The questionnaire consists of 53 symptom descriptions for which the patient rates the burden in the past week. The BSI has nine subscales. The total score indicates the general level over psychological/physical burden. A five-point scale is used for each item, ranging from *not at all* to *very much*. The scale with its subdomains is valid and reliable (Morlan ea, 1998).

Depressed mood. We will use the Beck Depression Inventory II (BDI 2) (Beck, Steer, & Brown, 1996; Beck, Steer, & Garbin, 1988). This self administered scale consists of 21 items that are each scored from 0 to 3. The total score ranges from 0 to 63, with higher scores indicating more depressed mood.

Finally, we will measure treatment preference within the therapists, and use this as a covariate in the analysis. Possible, preference makes a difference, and it is useful to account for this effect.

Study description

Background summary

Anxiety disorders are reinforced by anticipated danger, activated in the patient in certain situations. The association that a patient makes between stimulus and expected danger is in short called the CS-US association in learning-theoretical literature (Joos, Vansteenwegen, & Hermans, 2012). When

anticipating danger, patients will typically avoid the stimulus concerned (e.g. do not engage with social activities, or do not stand in de cue in the supermarket). Cognitive behavioral therapy aims to build safety associations as opposed to the negative CS-US, by cognitive restructuring and by learning new associations about the stimulus concerned through behavior change (Craske, Liao, & Vervliet, 2012). Thus, avoidance behaviors should be reduced and patients should be exposed to real life confirmations that the stimulus does not imply danger. It has been shown that a patient does not unlearn old memory representations. Rather, new safety associations will get stronger en inhibit the old memory representations concerning the response a stimulus will elicit (Craske et al., 2008). Thus, the association of social contact with a feeling of safety gets stronger than its association with danger. Based on theory on how cognitive behavior therapy works, it is said that negative and positive memory representations compete with each other for determining a person*s responses in terms of behavior, thoughts and feelings that a stimulus elicits (competitive memory retrieval account) (Brewin 2006). The idea is that CBT does not change the content of negative information, but rather changes the relative activation of positive and negative memory representations, in order to support the positive representations in being recollected from memory (Brewin 2006).

Cognitive behavioral therapy (CBT) is an effective treatment for anxiety disorders (Balkom van et al., 2013; Hofmann, Wu, & Boettcher, 2014). However, despite good effectiveness, there is still room for improvement (Hofmann, Fang, & Gutner, 2014). About 40% is cured by CBT, but 30% will keep suffering from severe symptoms despite intensive CBT (Durham, Higgins, Chambers, Swan, & Dow, 2012). Little is known about what makes these patients more vulnerable for poor treatment response. One possible obstacle is low self-esteem. Recently, based om 18 longitudinal studies, a meta-analysis has been conducted, examining causal relationships through time with sophisticated analyses. It turned out that low self-esteem is a cause of anxiety, as well as a consequence of it (Sowislo & Orth, 2013). This means that, even though the effects are small, both psychopathological phenomena reinforce each other. So there is evidence for the scar-model (anxiety disorders damage one*s self-esteem) as well as for the vulnerability model (low self-esteem renders someone more vulnerable for anxiety symptoms). An even more recent study (with 5.607 adolescents) found that the effects of family disadvantage and family functioning on social anxiety symptoms was explained in large part by lower elf-esteem (Yen, Yang, Wu, & Cheng, 2013). Another longitudinal study (1.641 high school students) found that low self-esteem predicted later anxiety symptoms, and not the other way around; anxiety symptoms did not predict a later low self-esteem (van Tuijl, de Jong, Sportel, de Hullu, & Nauta, 2014). The vulnerability model is therefore winning ground. Presumably, people with low self-esteem feel more insecure and less able to cope with stressful situations, they may experience less personal control and more selective pay attention to negative and fearful information instead of reassuring information that signals safety. Low self-esteem is presumably associated with vulnerability for stress, while people with a positive and stable self-image have more of a buffer for

stressful situations (Zeigler-Hill 2011). Patients with a weak and inferior self-image interpret situations and people as more threatening (Kesting & Lincoln, 2013).
The treatment of low self-esteem may exert a positive effect on anxiety symptoms, also when these symptoms do not respond to CBT. But, looking back at the CBT mechanisms outlined above, it is unclear what works best: strengthening positive memory representations or reducing negative memory representations. It is also not clear whether both approaches will have an additive effect for low self-esteem, and what the secondary effect on anxiety symptoms will be. Not much research has been conducted in this area.

In CBT terms, then, there are two treatment strategies possible for better self-esteem: to reduce or desensitize negative memory representations or enhancing or strengthening positive memory representations. There exist two therapy manuals in clinical practice that match these strategies:

- *EMDR second method* aims to reduce negative memory representations, by desensitizing three to five memories from someone*s past that for the patient still *prove* that he/she is worthless (or other negative self-belief).
- Competitive Memory Training (COMET) aims to strengthen positive memory representations by (1) enhancing the salience of the positive memory representations, (2) repeated activation, and (3) associating the positive representation to the negatively laden stimulus.

While *EMDR second method* has thus far not been investigated for it*s effectiveness on self-esteem, COMET has been proven effective in various patient groups, yet not specific for people with an anxiety disorder. The current research project will assess the effectiveness of both approaches in this patient group. Furthermore, this project will look at whether and when a combination is preferable over applying just one of these two treatment approaches.

Study objective

We want to answer the following research questions:

- Which of the mentioned treatment approaches is more effective for improving self-esteem?
- Do both approaches have additive value (does a patient benefit more after receiving both treatments, in comparison to receiving just one?)
- Does the order of conducting these two treatment approaches matter for the total effect?
- How do the treatment approaches exert their effect on positive and negative self-esteem as separate constructs? Are the expected specific effects confirmed by the data?
- Do subjective positive personal characteristics and experiences predict the success of COMET? Or if these factors are not present, does EMDR work better

than COMET?
- Will anxiety symptoms go down as self-esteem goes up? (it is only possible to perform an explorative analysis with the current study design)

Study design

A Randomized Controlled Trial (RCT) with a crossover design and two allocations. The two study allocations will receive this order of treatment modules:

1. First EMDR second method (6 sessions in 6-8 weeks) and then COMET (6 sessions in 6-8 weeks)
2. First COMET ((6 sessions in 6-8 weeks) and then EMDR second method (6 sessions in 6-8 weeks)

Patients will be informed about the study by their treating doctor of psychologist, or by professionals involved in the regular intake procedure. If the patient is interested, the Rosenberg Self-esteem Scale will be filled out in order to assess if the patient meets the basic inclusion criteria. The doctor/therapist will inform the patient about the study, verbally as well as on paper. After two weeks of time to consider, and if the patient agrees to have contact with there researcher, the coordinating researcher of that particular institution will contact the patient and ask if he/she wants to participate. If the patient agrees, an *informed consent* will be signed and the baseline measurement will be conducted. After that, the patient will be randomized to allocation 1 or 2.

Randomization
The randomization will be executed using a digital system (www.randomised.com), executed by the randomization bureau of Parnassia; a person that is not involved in the research project and works at a different location than the researcher. The randomization will be conducted with small batches of 4, stratified across the two institutions. This way, it is prevented that the mental health institution may constitute a confounding factor in the eventual data interpretation.

Measurements
At baseline, halfway, and after end of the treatment, measurements will take place using self-administered questionnaires. These questionnaires will be given and taken back in by an independent research assistant. This way, the patient can see that his/her therapist will not see the actual answers, and the risk of bias due to socially desirable answering is reduced.

Therapists, training and fidelity checks
The executing therapists are at least a psychologist and schooled in EMDR. Furthermore, they have experience with active CBT. They will be trained in the two treatment approaches of this study; two days in total, followed by

supervision of the ongoing therapies. All sessions will be recorded, unless a patient objects. A random sample of these recordings will be scored to assess fidelity to the treatment manual. Furthermore, the treatment preference of the therapist will be assessed, and included as a covariate in the analyses. Possible, preference makes a difference executing the treatment and it*s effectiveness, so it is useful to correct for this.

Intervention

EMDR second method is a well defined therapy, manuals existing in books and tought by the Dutch EMDR Association. EMDR stands for Eye Movement and Desensitization Reprocessing. It is an effective treatment for Posttraumatic Stress Disorder (Balkom van et al., 2013; Engelhard 2012; van den Hout, Rijkeboer, Engelhard et al., 2012). EMDR desensitizes vivid mental representations with negative emotionality (Shapiro n.d.). By using EMDR, these representations get reduced in their vividness and emotionality, and the memory content gets less accessible (van den Hout, Bartelski, & Engelhard, 2012). An underlying principle is that negative events leave their tracks in the memory of an individual in such a way that it causes symptoms, including dysfunctional beliefs about oneself (e.g. *I am a bad person*) or the world (*I am in danger*) (de Jongh, ten Broeke, & Meijer, 2010). By desensitizing negative memory content, low self-esteem can probably be treated, and this approach is known as *EMDR second method* (Broeke ten, Jongh de, & Oppenheim, 2012).

COMET stands for Competitive Memory Training and has in various studies proven to be effective in reducing low self-esteem as well as depression (Korrelboom, de Jong, Huijbrechts, & Daansen, 2009; Korrelboom, Maarsingh, & Huijbrechts, 2012; Korrelboom, Marissen, & van Assendelft, 2011; van der Gaag, van Oosterhout, Daalman, Sommer, & Korrelboom, 2012). COMET uses positive memories that encompass *counter-themes* of the current negative self-image. For example: if someone thinks of himself *I am incompetent*, then the counter-theme will be: *I am competent.* Representationts of this theme within that person*s autobiographical memory will by selected and then repeatedly relived as vividly as possible. This way the positive counter-theme becomes more active in the actual memory, inhibiting the negative memory representations, and improving self-esteem.

Study burden and risks

It will be expected of participating patients that they participate with the three assessments (that will take up about 60 minutes per assessment), in which they will answer questions about their psychological symptoms. Even though this is not fun to do, we known that there are no risks involved in these measurements. The scales and questionnaires have been used in research quite often and are safe to administer. This burden is not thought to be high or very taxing.

Next to the assessments, participants will receive two treatment modules, each consisting of six sessions of 45 minutes (12 sessions in total). The treatment will be provided by certified psychologists who have been trained to execute these treatment modules. Within these treatments, CBT techniques will be used to treat low self-esteem. In between the sessions, patients are asked to practice with these techniques in their daily life situations. So this comprises a larger burden than the assessments, yet this is regular within psychotherapy.

We do not expect any risks for the patients, concerning these assessments and treatment modules. The COMET therapy has been evaluated in six earlier intervention studies, without negative effects and with positive effects. These studies were concerned with various psychological conditions, e.g. depression and even psychosis (van der Gaag et al., 2012). A COMET version has also been applied to anxiety patients, without any negative effect (Korrelboom, Peeters, Blom & Huijbrechts, 2014). The EMDR procedure has been executed in clinical practive a lot, yet has not yet been investigated for self-esteem within anxiety.

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

- An anxiety disorder, based on a structured DSM-IV interview
- Low self-esteem (< 26 on the Rosenberg Self-esteem scale)
- For one month or more: no changes in psychopharmacological medications
- Mastery of the Dutch language, in order to be able to fill out the questionnaires
- Able to mention at least one positive aspect within his/her self-image, which does not need to be felt or be completely convincing ;- In Altrecht Psychiatric Institute, an extra criterion is that the anxiety disorder has received at least 12 sessions of regular evidence-based therapy (according to the guidelines: cognitive behavioral therapy or medication). Despite the treatment, anxiety symptoms still remain in the psychopathological range, as assessed by scoring 39 or higher on the state-part of the STAI (Julian 2011). The disorder has thus not been taken away as a result of the regular treatment.

Exclusion criteria

- Drug abuse or dependance according to DSM-IV criteria
- Severe depression according to DSM-IV criteria
- Psychotic disorder according to DSM-IV criteria

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-05-2014
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	08-05-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	23-06-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 26034
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL47772.041.14
OMON	NL-OMON26034