SETA trial

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26034

Source
NTR

Brief title
SETA trial

Health condition

Anxiety disorders
Self-esteem

Angststoornissen
Zelfbeeld
Zelfwaardering

Sponsors and support

Primary sponsor: University of Utrecht, The Netherlands.
Prof. Dr. I Engelhard.
Source(s) of monetary or material Support: Fund = initiator = sponsor. No external funding source as yet.

Intervention

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).

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).

Secondary outcome

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.

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).

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

Study description

Background summary

Cognitive behavioural therapy will cure about 40% of patients of their anxiety disorder, yet 30% will still be left with a severe anxiety disorder. In anxiety disorders, low self-esteem often plays a role, especially when the disorder is more complex or in the case of a co-morbid depression. Based on underlying theory about the working mechanisms of cognitive

behavioural therapy, it has been assumed that negative and positive memory representations compete with each other in determining a person's responses to stimuli in terms of thoughts, feelings, and behaviours (competitive memory retrieval account). However, it is unclear which works better for self-esteem treatment: enhancing positive memory representations or reducing negative memory representations. Also, it is not known whether both approaches exert a complementary effect, or what the effect is on anxiety symptoms. We aim to answer these questions by treating 60 patients with an anxiety disorder with two self-esteem treatments: one to reduce negative memory representations ('EMDR second method approach') and one to enhance positive memory representations (COMET). Patients will be randomly allocated to treatment A or B, and after six sessions these treatments will be swapped (randomized controlled trial with a cross-over design). Self-esteem, including its positive and negative aspects, and also anxiety symptoms are the primary outcome measures and will be measured at three time points. Secondary outcomes are depression and general psychopathology.

Study objective

We want to answer the following research questions (we do not know the direction of effect (which of the two methods works better) and therefore have no hypotheses):

- 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?
- What is the effect of an improved self-esteem on anxiety symptoms?
- 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?

Study design

At baseline (T0), halfway (T1), and after end of the 12 session complete treatment (T2), measurements will take place using self-administered questionnaires.

Intervention

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)

'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.

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Eligibility criteria

Inclusion criteria

People with a primary anxiety disorder according to the DSM-IV, possibly more than one anxiety disorder, co-morbid depression and/or other co-morbid symptoms. So co-morbidity is not an exclusion criterion.

Further inclusion criteria are:
– 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

At Altrecht psychiatric institute, there is an extra inclusion criterion: the anxiety disorder has been treated for at least 12 sessions with regular evidence-based therapy. Despite this, anxiety symptoms are still present in the psychopathological level, as shows by scoring 39 or higher on the state part of the STAI instrument (Julian, 2011). Thus, the disorder has not responded well enough to regular treatment. At the other participating institution, PsyQ, this criterion is not applied. There, patients may participate in the study right after intake procedure. This difference is a consequence of available patients groups and the vision of therapists and researchers of both institutions. However, despite the fact that the selected patient groups will not be completely comparable, a broader population will enter the study this way, which has benefits. And it is not the goal to compare the two institutions.

Exclusion criteria

– Drug abuse or dependance according to DSM-IV criteria

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2014
Enrollment:	60
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 40665
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4297
NTR-old	NTR4441
CCMO	NL47772.041.14
OMON	NL-OMON40665

Study results

Summary results
No publications of this trial yet. We will aim to publish the outcome of the trial in an English

journal. Our current research group has experience and publications on this particular topic however, e.g. by Prof. Dr. I. Engelhard and Dr. C.W. Korrelboom.