Efficacy of visual art therapy on anxiety symptoms in adult women

No registrations found.

Ethical review Not applicable **Status** Recruiting

Health condition type -

Study type Interventional

Summary

ID

NL-OMON27381

Source

Nationaal Trial Register

Health condition

anxiety disorders:

- generalised anxiety disorder (GAD)
- social phobia
- panic disorder (with or without agoraphobia)

Angststoornissen (ICPC P74.01/02)

- gegeneraliseerde angststoornis
- sociale fobie
- paniekstoornis (met of zonder agorafobie)

Sponsors and support

Primary sponsor: University of Applied Sciences Leiden

Leiden University

Source(s) of monetary or material Support: NVKT

Intervention

Outcome measures

Primary outcome

1 - Efficacy of visual art therapy on anxiety symptoms in adult women 6-06-2025

anxiety symptoms

Secondary outcome

- quality of life
- emotion regulation
- executive functioning

Study description

Background summary

Background:

For anxiety disorders as GAD, social phobia and panic disorder, treatment results of standard care are less successful then for other anxiety disorders. Investigating the effectiveness of other types of therapies is needed. RCTs are important for establishing efficacy of interventions. For anthroposophic art therapy, no RCT has been executed. Treatment of anxiety in adults is one of the best practices of AAT, according to therapists. An important reason for organizing/conducting an efficacy study.

Method: a single-blind randomized controlled trial (RCT) with repeated measures will be performed for this intervention research.

Study Population

Participants are recruited by social media and posters/flyers in the practices of general practitioners.

Women with a moderate to severe anxiety symptoms (scoring >7 for anxiety and >10 for distress on the 4DKL(2)), aged between 18-65 years, ability to fill in questionnaires on a computer and a written informed consent belong to the inclusion criteria. Patients are excluded if they are aged less than 18 years or older than 65 years, have psychosis or hallucinations, drug dependence, pacemaker, or receive eurythmic or rhythmical massage therapy during study period.

The following diagnoses will be included: generalized anxiety disorder, social phobia and panic disorder (with or without agoraphobia), established by a diagnostic interview (MINI-plus).

Patients without one of these diagnoses are excluded.

Prestratification and Randomisation

Enrolled participants are divided into four strata: whether or not using psychotropic drugs, and whether or not having moderate or severe depression symptoms (4DKL: depression >6), and subsequently assigned to treatment (AT) or control group (WL) by means of block randomization.

We aim at a treatment group (art therapy: AT) and a control group of 30 participants each. The control group is a waiting list group (WL) that will not be treated with AAT for three months. After three months, the control group receives the therapy, making the total treatment group size 60.

Intervention

After randomization 30 AT patients will receive ten to twelve individual art therapy sessions of 45 to 60 minutes per session during three months. Treatment is provided by qualified and registered art therapists.

Study parameters

Primary outcome measure is anxiety level (LWASQ) and stressresponsivity (psychophysiological protocol: ECG and skin conductance).

Secondary outcome measures are: quality of life (MANSA), emotion regulation (DERS) and executive functioning (BRIEF-A, ANT).

Measurements will be executed:

Month 0: T0, before the start of the therapy (AT), or before start of waiting list (WL)

Month 3: T1, after three months of therapy (AT), or after three months waiting time (WL)

Month 6: T2, three months after ending of the therapy (AT), or after three months of therapy (WL)

Study design

T0: before start therapy / start waiting time

T1: after therapy / after waiting time (3 months)

T2: follow up after three months

Intervention

visual art therapy; anthroposophic art therapy

Contacts

Public

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Eligibility criteria

Inclusion criteria

- Leeftijd: 18-65 jaar
- Angstsymptomen: score op 4DKL: verhoogd op angst (>7) en/of verhoogd op distress (=10/>10)
- Diagnose: vast te stellen mbv MINI-plus diagnostisch interview (P074.02, P074.01)

Exclusion criteria

- alcoholmisbruik, drugsverslaving (vast te stellen mbv MINI-plus diagnostisch interview)
- pacemaker (ivm vertekening fysiologische metingen) (vast te stellen dmv telefonische screening)
- scores 4DKL: angst =7/<7 en/of distress <10

• Diagnose: OCD, PTSS of alleen een specifieke fobie

Study design

Design

Study type: Interventional

Intervention model: Crossover

Allocation: Non controlled trial

Masking: Single blinded (masking used)

Control: Active

Recruitment

NL

Recruitment status: Recruiting
Start date (anticipated): 03-04-2017

Enrollment: 62

Type: Anticipated

Ethics review

Not applicable

Application type: Not applicable

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 NL6661 NTR-old NTR6838

Other NL61366.058.17 : CME LUMC

Study results