Efficacy of art therapy on anxiety symptoms in adults

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

Summary

ID

NL-OMON45474

Source
ToetsingOnline

Brief title
ARTANX

Condition

- Anxiety disorders and symptoms

Synonym
anxiety disorders, anxiety symptoms

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: Ministerie van OC&W,Nederlandse vereniging voor kunstzinnige therapie (NVKT)

Intervention

Keyword: Anxiety, Art therapy, Efficacy

Outcome measures

Primary outcome

Anxiety level (through self-assessment questionnaire and stress responsivity measurements (physiological parameters: heart rate and skin conductance)).

Secondary outcome

Quality of life (self assessment), Emotion regulation (self-assessment), executive functions (self-assessment and cognitive tasks) and specific aspects of artistic work, determined using AT checklists.

Study description

Background summary

Anxiety disorders are several disorders with an "abnormal" experience fear, which fear gives rise to sustained subjective distress and / or an obstacle to social functioning. Among these disorders are panic disorder, social phobia, agoraphobia, specific phobia, obsessive-compulsive disorder (OCD), post traumatic stress disorder (PTSD) and generalized anxiety disorder (NHG standard anxiety 2012 (Hassink-Franke, Terluin, Heest, of, Hekman, Marwijk, van & Avendonk, of, 2012)). The prevalence of anxiety disorders in the population is high (7.7% of men and 12.5% **of women).
Anxiety disorders lead to reduced quality of life and functional impairment, also at work (Kouzis, 1994; Kessler, 1997; Deura, 2000). Anxiety disorders are also associated with substantial personal and societal costs. Although there are effective methods of treatment, for example, for PTSD and OCD, in some anxiety disorders, including generalized anxiety disorder and social phobia, these methods have less successful treatment results (Newman, Llera, Erickson, Przeworski & Castonguay, 2013). It is therefore of interest to look at other, new treatment options.
One of these options is art therapy (AT). The multidisciplinary guideline for anxiety disorders of the Trimbos Institute (2013), visual art therapeutic interventions are described as potentially effective treatments. This includes anthroposophic Art Therapy (AT). AT uses color and form as 'impressions' that

are supposed to act on the health of the client, which is designed to exert a rebalancing effect on the physical, psychological and individual-biographical aspects of the patient. AT is applied already since the beginning of the last century in various disorders. There is much experience in the treatment of anxiety disorders. However, there has been little research on the effects and operation of AT in anxiety disorders. To understand the potential value of AT and its possible place in the existing treatment services, thorough empirical research is needed.

Study objective

The primary objective of the study is to determine what changes with regard to anxiety level and perceived quality of life occur in patients with anxiety treated with art therapy (AT) for three months.

Secondary objective is to explore mechanisms (stress respons, emotion regulation and executive functioning) that can substantiate the possible effects of AT on anxiety symptoms and quality of life.

The research questions of the study are:
1) What are the effects of AT on anxiety levels and quality of life?
2) What possible working mechanisms can contribute to a possible effect of AT?

It is expected that AT through stress reduction has a positive effect on anxiety levels and the quality of life and that there can be small improvements in the areas of executive functioning and emotion regulation.

Study design

Exploration within a single-blind randomized controlled trial (RCT) with repeated measurements, combined with research aimed at identifying predictive factors in the treatment group. Enrolled participants are divided into four strata: whether or not using psychiatric drugs, and whether or not having moderate to severe depression symptoms (4DKL: depression score> 6), and subsequently assigned by means of block randomisation to treatment or control group (3 months wait list). After three months, the control group will also recieve the treatment.

Intervention

Art therapy (AT),10-12 sessions (treatment period: 3 months). The therapist makes an individual treatment plan after an intake and 1-3 free artistic works. The therapists offer various visual art methods and techniques that are intended to reduce anxiety symptoms. The following AT techniques are given to the patients (Tit-Chris Marker & Mees 2009): drawing from observation,light-dark exercises with charcoal, dynamic drawing and solid body

clay modeling (series of cube to octahedron (Geuskens, 2014)).

Study burden and risks

All participants will continue treatment as usual. AT is used as additional therapy. Half of the participants is on a waiting list for three months. All participants follow initial screening (T0) with the 4DKL: 10 minutes. The measurements regard a psychodiagnostic interview (MINI-plus, 30 min), cognition (ANT: BS (alertness), SAD (sustained attention), SSV (inhibition and mental flexibility): a total of 30 min), questionnaires (LWASQ, MANSA, DERS, BRIEF) and physiological measurements (heart rate and skin conductance). These measurements take a maximum of 2 hours to complete, including a break.

Posttest after 3 months consists of the same elements, without the psychodiagnostic interview. This measurement therefore takes up to 1.5 hours. The delayed post-test after 6 months only consist of questionnaires (4DKL, LWASQ, MANSA, DERS, BRIEF) and takes about 40 minutes. All participants who completed the therapy are then asked whether they want to participate in an open interview of up to 1 hour. For participants in the treatment group, there is a time investment of 10 to 12 therapiesessions of 45-60 minutes..

For participants in the control group (waiting list), there is also the possibility, after three months, to follow the therapy. Again, this is a time investment of 10 to 12 AT sessions each lasting 45-60 minutes.

Benefit for the participants is that they participate in a non-verbal treatment aimed at reducing anxiety. The effect of the treatment could be that the participant will need more information or guidance. If this is the case, the participant is referred to the own treatment coordinator (general practioner or other).
Physiological parameters (stressresponsivity) are measured with Biopac equipment, in which patches are stuck on the skin and fingers. It is a non-invasive measurement. Evoking stress while physiology protocol could have negative consequences for the participant. When stress levels do not return to baseline at the end of the measurement, the caretaker of the participant will be contacted.

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

- Age: 18-65
- Anxiety symptoms (present), measured by score on 4DKL questionnaire: Anxiety > 7 and/or Distress <=10/>10
- Diagnosis: GAD, social phobia, panic disorder (with or without agora phobia)

Exclusion criteria

- Alcohol abuse, drug abuse (assessed by means of the MINI-plus diagnostic interview)
- Pacemaker (bias physiological measurement)
- Score on 4DKL questionnaire: Anxiety =7/ <7 and/or Distress <10
- OCD, PTSD or a specific phobia (assessed by means of the MINI-plus diagnostic interview)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-11-2017
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	17-11-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL61366.058.17