Effectiveness of Autonomy-Groups in Patients with Anxiety Disorders: A RCT. Effectiviteit van Autonomiegroepen in Patiënten met Angststoornissen: Een RCT.

No registrations found.

Ethical review Positive opinion

Status Recruitment stopped

Health condition type -

Study type Interventional

Summary

ID

NL-OMON27333

Source

Nationaal Trial Register

Health condition

Anxiety, Anxiety disorders, Angst, Angststoornissen

Sponsors and support

Primary sponsor: Tilburg University, GGZ inGeest, VU-University Medical Centre

Source(s) of monetary or material Support: VSB Fund

Intervention

Outcome measures

Primary outcome

- 1. The three subscales of the Autonomy-Connectedness Scale 30 (ACS-30);
 - 1 Effectiveness of Autonomy-Groups in Patients with Anxiety Disorders: A RCT. Eff ... 31-05-2025

2. The total score on the Symptom Checklist 90 (SCL-90).

Secondary outcome

- 1. Subscales of the Symptom Checklist 90 (SCL 90);
- 2. Anxiety: Fear Questionnaire (FQ);
- 3. Depression: Beck Depression Inventory-II (BDI-II);
- 4. Eating Disorder: Eating Disorder Examination-questionnaire (EDE-Q);
- 5. Quality of life: WHO Quality of Life BREF (WHOQOL-BREF);
- 6. Self esteem: Rosenberg Self-Esteem Scale (RSE).

Study description

Background summary

The aim of this study is to examine the effect of autonomy-groups in patients with anxiety disorders. This study uses a Randomized Controlled Trial (RCT) design. There will be two groups of patients with anxiety disorders, the AGs and the control-groups (waiting list) and three measurement moments: before, halfway, and at the end of treatment. Participants fill out several questionnaires concerning autonomy-connectedness and mental health.

Patients will be recruited in the Netherlands.

Study objective

- 1. Patients with anxiety disorders show an increase of autonomy after the Autonomy-Group treatment;
- 2. Patients with anxiety disorders show a decrease of their symptoms after the Autonomy-Group treatment.

Study design

Before treatment (T1), halfway (7 weeks, T2) and after treatment (15 weeks, T3).

Intervention

2 - Effectiveness of Autonomy-Groups in Patients with Anxiety Disorders: A RCT. Eff ... 31-05-2025

Intervention, Autonomy Group:

The treatment is aimed at increasing autonomy by means of a protocol developed for this study. There are 15 sessions of AGs each offered once in a week, taking 2 to 2,5 hours. Every group has an average of 8 to 10 patients.

Control:

The control group consists of patients on a waiting list. The duration of the waiting list is the same as that of the intervention group: 15 weeks.

Contacts

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Eligibility criteria

Inclusion criteria

- 1. > 18 years old;
- 2. Diagnosis of one or more anxiety disorders according to DSM IV TR. Main diagnosis has to be an anxiety disorder.

Exclusion criteria

Having a main diagnosis of obsessive compulsive disorder or post traumatic stress disorder, psychosis, addiction, suicidal thoughts or attempts, acute mourning or crisis or mental retardation.

Study design

Design

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Single blinded (masking used)

Control: Placebo

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-09-2012

Enrollment: 76

Type: Actual

Ethics review

Positive opinion

Date: 22-06-2012

Application type: First submission

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 NL3365 NTR-old NTR3513

Other METc VUmc : 2011/98

ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A