Effectiveness of Autonomy-Groups in Patients with Anxiety Disorders: A RCT

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ObjectiveTo investigate the effectiveness of autonomygroups for (Dutch) patients with anxiety disorders.Research questions(1) *Do patients with anxiety disorders show a significant increase of autonomy after the autonomygroup?*(2) *Do patients with...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39159

Source
ToetsingOnline

Brief title
Effectiveness of Autonomy-Groups

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym
anxiety disorders, fear

Health condition

autonomie problemen

Research involving
Human

Sponsors and support

Primary sponsor: GGZ inGeest (Amsterdam)
Source(s) of monetary or material Support: Ministerie van OC&W,VSB-fonds

Intervention

Keyword: anxiety disorders, autonomy, RCT

Outcome measures

Primary outcome

Instruments

- Demographical information

Questions are asked about the demographic background of the patient, like age, gender, professional and employment status, the country of birth of the patient and his/her parents, and therapies the patient has had in the past.

- Autonomy-Connectedness Scale (ACS-30; Bekker & van Assen, 2006)

has 30 items to be answered on a 5-point scale with answering possibilities ranging from 1 (disagree) to 5 (agree). These 30 items make up 3 scales, namely Self-Awareness, Sensitivity to Others, and Capacity of Managing New Situations.

- Beck Depression Inventory (BDI; Beck at al., 1961)

measures the extent to which various aspects of depression are being suffered. The scale has 21 items all with a 4-point scale, with answer possibilities ranging from 0 (not feeling*) to 3 (feeling so* that I cannot endure it).

- Symptom Checklist-90 Revised (SCL-90R; Derogatis, 1977)

is very closely related to the original SCL-90 questionnaire. The SCL-90 is a multi-dimensional self-report inventory, consisting of 90 items covering 8 dimensions of psychological distress: phobic anxiety, anxiety, depression,

somatization, obsessive-compulsitivity, distrust and interpersonal sensitivity, hostility and insomnia. Each item describes a physical or psychological symptom whereby the patient is asked to indicate the extent he/she has felt this symptom during the preceding week. The answer possibilities are ranging from 1 (not at all) to 5 (extremely).

- WHO Quality of Life *BREF (WHOQOL-BREF; De Vries & Van Heck, 1995)

is a shorter version of the WHO Quality of Life-100 instrument. The WHOQOL-BREF instrument has 26 items, which measures the following broad domains: psychical health, psychological health, social relationships, and environment. The response scale is a 5-point Likert scale; dependent on the question ranging from 1 to 5 (for example, the question **How satisfied are you with your health?* can be answered ranging from 1 (very dissatisfied) to 5 (very satisfied))..

- Fear Questionnaire (FQ; Marks & Mathews, 1979)

consists of 21 questions; one question about the main fear of the patient, three subscales (consisting of 15 items) about agoraphobia, social phobia, and blood phobia. Patients need to answer to what extent they would avoid the described situation on a 9-point Likert scale (0= would not avoid, 8=always avoid it). The last 5 questions are about fear and depression.

- Rosenberg Self-Esteem Scale (RSE; Rosenberg, 1965)

measures the overall feeling about self-image and has 10 items to be answered on a four point scale from strongly agree to strongly disagree. Examples are: *at times, I think I am not good at all*; and *I am able to do things as well as most other people*.

Outcome of the study: reduction of the symptoms that will be measured by questionnaires mentioned above, and an increase of the autonomy level, which will be measured with the autonomy scale.

Secondary outcome

not applicable

Study description

Background summary

Concept of Autonomy (-Connectedness)
In Western culture, autonomy is considered to be a successful and healthy outcome of the process of becoming an adult person. In that case, the process covers good attachment experiences in early childhood, and the person acquires the capacity of maintaining a good balance between dependence and separation (e.g., Bowlby, 1969; 1973; Mahler, Pine & Bergman, 1975). The modern concept of autonomy contains both the awareness of one*s goals, wishes and needs and the ability to realize these, and the capacity to start and maintain meaningful social relationships. As the ability to maintain relationships is also labeled **connectedness**, the term **autonomy-connectedness** is a more adequate and complete term for what the concept refers to (Bekker & van Assen, 2006). Autonomy-connectedness has three components. The first one is Self-Awareness, defined as the capacity to be aware of one*s own opinions, wishes, and needs, and the capacity to express these in social interactions. The second component, Sensitivity to Others, is the sensitivity to the opinions, wishes, and needs of other people; empathy; and capacity and need for intimacy and separation. The third component, Capacity for Managing New Situation, stands for (un)-easy feeling in new situations, flexibility, tendency to explore, and dependence on familiar structures (Bekker & van Assen, 2006). From the attachment theory perspective, this drive for exploration follows from secure attachment.

Autonomy-connectedness is related to attachment-styles, gender, and several mental disorders
Autonomy development is based on experiences with attachment-figures, started from early childhood (Bekker, 1993; 2008). In short, two styles can be distinguished: secure and insecure attachment. A secure attachment style results from good and positive interpersonal experiences. The child experienced availability and adequate responses from the primary attachment figure when needed. Insecure attachment is a result of negative interpersonal experiences, in which the child did not experience consistent availability and adequate

responses from the primary attachment-figure.
Autonomy problems are related to insecure attachment styles, such as avoidant and anxious attachment (e.g., Bekker, Bachrach & Croon, 2007). In the case of avoidant attachment, a relatively low self-awareness coincides with extreme low sensitivity to others, and in the case of anxious attachment, low self-awareness goes together with extremely high sensitivity to others. Insecure attachment and autonomy problems as well as their sex differences are clinically relevant. Although relatively high levels of sensitivity to others might belong to the normal feminine identity, extremely high sensitivity to others reflecting neediness (Rude & Burnham, 1993) is a risk factor for psychopathology with a higher prevalence in women than in men, e.g., depression and anxiety (Bekker & Belt, 2006; Bekker & Croon, 2010) and eating disorders (Van Loenhout, Bekker, & Kuipers, under review). In a similar way, under-sensitivity to others might substantially affect psychopathology with a higher prevalence in men. For example, antisocial behaviour might be affected by extreme tendencies toward detachment and separation, i.e., by under-sensitivity to others, especially to potential victims (e.g., Bekker, Bachrach & Croon, 2007; Hoffmann, Powlishta, & White, 2004).

Autonomy-connectedness and mental health care: The need for empirical support
Practice-based evidence shows that autonomy deficits are related with mental disorders, particularly those characterized by oversensitivity to others, with a higher prevalence among women (e.g., anxiety disorders, depression, and eating-disorders). Consequently, AGs were provided as a therapy, in the Netherlands from 1970, to women with autonomy problems. Also here, autonomy problems were usually defined as problems with (a) one*s self-awareness or identity; (b) the ability to set and/or express boundaries to others; (c) one*s over-sensitivity and/or over-responsibility to others; and (d) decision making (Bekker, 1993; 2008).
The therapeutic results of these AGs are generally considered very promising, but up till now, only one pilot study (van Houten & Vossen, 2008) has been conducted that focused on the effect of autonomygroups. It appeared that AG with patients with severe anxiety-disorders who had insufficiently profited from cognitive-behavior therapy, reduced their anxiety- and other related problems to a large extent. Yet, this study had no control-group, and its sample size was very low (N=6). Clearly, more research is needed to show the effectiveness of the AG. This is an important target when taking into account the current emphasis on the necessity of **evidence-based** treatment.
Patients within autonomygroups usually have different types of symptoms and disordes and therefore make up a heterogeneous group, which makes effectiveness study somewhat complex. In this study, the effectiveness of autonomygroups will be examined with patients of a more homogenous group, to overcome this complexity. According to Bekker and Croon (2010), autonomy-connectedness seem very important in treating anxiety. In the Netherlands, there are several GGZinstitutions, including GGZiIngeest, that offer autonomygroups specifically to patients with anxiety disorders for some years now. Hence, this study

focuses on the effectiveness of AGs for patients with anxiety disorders.

Study objective

Objective
To investigate the effectiveness of autonomygroups for (Dutch) patients with anxiety disorders.
Research questions
(1) *Do patients with anxiety disorders show a significant increase of autonomy after the autonomygroup?*
(2) *Do patients with anxiety disorders show a significant decline in their symptoms after the autonomygroup?*
Hypotheses
(1) Patients with anxiety disorders show an increase of autonomy after the autonomygroup..
(2) Patients with anxiety disorders show a decrease of their symptoms after the autonomygroup.

Study design

Procedure:
Dutch GGZ institutions (including GGZ inGeest at Amsterdam) that offer Autonomy Groups (AG) to patients with anxiety disorders will be involved in this study. Patients meeting inclusion and exclusion criteria are asked to participate in the study. AG*s consist of 15 sessions once in a week, taking 2 to 2,5 hours. Every AG has an average of 8 patients with a maximum of 10. Patients are randomised over two conditions: AG and a control-group (waiting list). In this study, a Randomized Controlled Trial (RCT) design is used. Measurements will take place at 3 moments (before the treatment (T1), half way the treatment (T2), after the treatment (T3). Before each measurement the researcher will deliver the envelopes with the questionnaires to the therapist, who will hand out the envelopes to their patients within the autonomygroup. These patients will be offered time to fill in the questionnaires at the GGZ inGeest. After filling in the questionnaire, the patients will be asked to put the filled-in questionnaires back into the envelope and return it to their therapists. Regarding the control-group, the secretary within GGZ inGeest will send the envelopes to the patient*s home addresses, where they can fill in the questionnaires, After filling in, the patients can return the filled-in questionnaire back to GGZ inGeest with a retour-envelop which is included.
Ethical issues: For medical ethical reasons, patients will be informed about the research during the intake-procedures. Shortly before the therapy starts, all patients in the AGs receive additional information in which all steps of the research are being explained. In addition, the informed consent is included, in which the patients can confirm their commitment to the research. Furthermore, the patients will be informed about the three times of measurements during the treatment. This means that some identification of the

patients is needed to connect the data of the several measurements with the right patient. Therefore, in each measurement the patient is asked to write down his/her name. It is guaranteed that the patient*s name will be removed immediately after the data collection. Finally, patients are also informed that there will be no consequences when they decide, during the therapy, not to participate the study any longer; the patients are able to continue the therapy. The control-group will receive the same information as the patients in the autonomygroup together with some extra information explaining the design of the study, and why it is important that they wait for 15 weeks before they receive their treatment. In addition, they will get the opportunity to let know whether they agree with this design, or when (at a later stage) they no longer want to participate. In addition, when in their opinion the waiting period is too long, they will be either offered the treatment as soon as possible, or another treatment that is comparable to the AGs. Filling in the set of questionnaires (in each measurement) will take 1 hour. Finally, the therapists will not see the filled-in questionnaires of the patients. Only the researcher will see their names when relating the names with numbers. After the data collection, the names will be removed from the system. The filled-in questionnaires will be property of the GGZinstitutions..

Intervention

Patients randomised to the intervention condition receive a grouptraining to increase their autonomy. They recieve 15 sessions of 2 hours.
Patients randomised to the controlcondition do not receive treatment ('waitinglist control condition').

Study burden and risks

not applicable

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

Diagnosis of one or more of the following anxiety disorders according to DSM-IV: panic disorder with/without agoraphobia, social anxiety disorder, generalised anxiety disorder.

Exclusion criteria

Having (a history of) psychosis; addiction; suicidal thoughts or attempts; acute mourning or crisis ; mental retardation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-08-2012
Enrollment:	76
Type:	Actual

Ethics review

Approved WMO Date:	16-02-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-05-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL35290.029.11