The efficacy of a CBT relapse prevention program for remitted anxiety disorder patients who discontinue antidepressant medication.

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The aims are threefold: i) to assess the efficacy of a cognitive behavioural group (CBT) intervention in reducing relapse rates in remitted anxiety disorder patients who discontinue AD, as compared with AD discontinuation alone; ii) to investigate...

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

Summary

ID

NL-OMON37997

Source
ToetsingOnline

Brief title
Intervention study anxiety disorder patients.

Condition

- Anxiety disorders and symptoms

Synonym
anxiety disorders; anxiety

Research involving
Human

Sponsors and support

Primary sponsor: GGZ inGeest (Amsterdam)

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: antidepressants, anxiety disorders, secondary prevention, treatment efficacy

Outcome measures

Primary outcome

Primary outcome measure is relapse within a year.

Secondary outcome

Secondary outcome measures are i) time to relapse; ii) one-year course of anxiety symptoms; iii) quality of life; iv) patient satisfaction; v)predictors of relapse; vi) cost-effectivity; and vii) cost-utility.

Study description

Background summary

To improve the long-term course of anxiety disorders, relapse prevention should be an integrated part of treatment. As discontinuing antidepressants (AD) is associated with high relapse rates, relapse prevention is even more important in patients who discontinue AD. This study is proposed because cost-effective evidence-based strategies aimed to prevent relapse after discontinuing AD are lacking.

Study objective

The aims are threefold: i) to assess the efficacy of a cognitive behavioural group (CBT) intervention in reducing relapse rates in remitted anxiety disorder patients who discontinue AD, as compared with AD discontinuation alone; ii) to investigate predictors for relapse to enable further specification of those at highest risk; iii) to calculate cost-effectivity and cost-utility of the intervention.

Study design

The efficacy will be studied in a multicenter randomized controlled trial with 220 patients with anxiety disorders in remission. After the intervention,

relapse will be followed monthly for one year. Predictors of relapse are assessed at baseline and after the intervention, at 4 months after baseline. For economic analysis, three monthly assessments will take place. A pilot study to test the protocol is being conducted.
Sample size calculation
110 Patients will be included in each condition, based on an estimated effect size of 0.50, a power of 0.80 and a 2-sided p-value of 0.05.
Economic evaluation
Analyses are undertaken from a societal perspective. Both direct and indirect costs are calculated. A cost-efficacy analysis assesses the costs per relapse prevented. A cost-utility analysis assesses the costs/QALY gained.
Time schedule
Eight months inclusion, four months intervention, one year follow-up.

Intervention

The intervention consists of AD discontinuation and CBT in a group format. Based on prior research, efficacy is assumed. The control intervention consists of AD discontinuation alone.

Study burden and risks

We presume that there are no risks. The burden consists of time spend for the psychological screening involving questionnaires and interviews.

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

Included are adults aged 18-65 years i) who use AD for panic disorder (with or without agoraphobia), social phobia or generalized anxiety disorder; ii) who are in remission; and iii) who want to discontinue AD.

Exclusion criteria

Patients with a comorbid dementia, psychotic disorder, alcohol or drug dependence or who do not speak Dutch are excluded.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-09-2010

Enrollment:	220
Type:	Actual

Ethics review

Approved WMO Date:	03-03-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-03-2012
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	NL30576.029.09