A relapse prevention study for anxiety patients who want to discontinue antidepressant medication.

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21398

Source
Nationaal Trial Register

Brief title
Intervention stydy anxiety disorder patients

Health condition

Remitted anxiety disorder patients: panic disorder with of without agoraphobia, social phobia and generalized anxiety disorder

Sponsors and support

Primary sponsor: GGZ InGeest (partner van VUMC)
Source(s) of monetary or material Support: GGZ InGeest (partner van VUMC)
Zon Mw

Intervention

Outcome measures

Primary outcome

The primary outcome measure is relapse within a year.

Secondary outcome

1. Time to relapse;

2. One-year course of anxiety symptoms;

3. Quality of life;

4. Patient satisfaction;

5. Predictors of relapse;

6. Cost-effectivity;

7. 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 evidence-based strategies aimed to prevent relapse are lacking. The aims are threefold:

1. 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 tapering;

2. To investigate risk factors for relapse to enable further specification of those at highest risk;

3. To calculate cost-effectivity and cost-utility of the intervention.

Study design:

The efficacy will be studied in a multicenter randomized controlled trial with 110 patients in both the intervention and the control group. Course of anxiety will be followed every three months for one year. Risk factors are assessed at baseline and post-intervention. For economic analysis, three monthly assessments will take place. A pilot study to test the protocol is being conducted.

Study population:

Included are adults aged 18-65 years who use AD for panic disorder, agoraphobia, social phobia or generalized anxiety disorder, but who are in remission and want to discontinue AD. Patients with dementia, psychotic disorder, alcohol or drug dependence/ or who do not speak Dutch are excluded.

Intervention:

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

Outcome measures:

Main outcome criteria are:

1. The proportion of patients with a relapse within a year;

2. Time to relapse.

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. Binominal tests will be used to test differences in relapse rate. Time to relapse and factors predicting time to relapse will be studied with survival analysis.

Economic evaluation:

Economic 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.

15-apr-2015: This RCT was terminated preliminary after conducting an interim analysis. The interim analysis was not planned before the start of the trial. The analyses was conducted for ethical reasons, when 89 participants were included. In both the intervention group as well as the control group antidepressant medication was tapered down. We expected the cognitive behaviour therapy (CBT) intervention to prevent relapse. However, during the trial we observed the following events which gave us reason to install an independent data monitoring committee to conduct the interim analysis:

- We observed more relapses than to be expected, in both groups, within 3 months after tapering down the antidepressant medication.

- Patients did not only have a relapse of their former anxiety disorder, but in several cases they developed new anxiety disorders or depressive disorders

- After relapse, some patients restarted antidepressant medication, but did no longer respond to the medication.

- A significant effect of the intervention was no longer expected, due to the calculated effect size of the intervention with this number of participants.

The independent data monitoring committee statistically analysed the relapse rates in both groups blindly, calculated the effect size between the two groups and the number of participants needed to reach a possible significant effect. Based on these analyses, the committee informed the principal investigator, who decided to stop the trial prematurely.

Study objective

The hypothesis is that offering CBT in a group format while discontinuing antidepressant medication will reduce the high relapse rates in remitted anxiety disorder patients who discontinue pharmacological treatment.

Study design

Diagnostic status is assessed at baseline to verify remission. To assess relapse and time to relapse, diagnostic status is verified every 3 months until one year after the intervention. Likewise, to investigate the one-year course of anxiety symptoms, anxiety questionnaires are administered every three months until one year after the intervention as well. To investigate effects of the intervention on quality of life and patient satisfaction, these aspects are assessed at baseline, after the intervention (at 4 months) and at a one-year follow-up in face to face interviews. To study predictors of relapse, many potential predictors will be assessed at baseline. Those predictors that may change due to intervention will also be measured after the intervention, thus at 4 months. Discontinuation symptoms have been suggested as a risk factor for relapse. These will be assessed at each session during the intervention in both conditions. To conduct economic analyses, health service uptake, work loss and quality of life will be assessed every three months until the one-year follow up.

At baseline remission is verified using the SCID (Structured Clinical Interview for DSM-IV Axis I Disorders). To assess relapse and time to relapse, diagnostic status is verified every 3 months by a telephone interview until one year after the intervention, using the SCID section of the initial anxiety diagnosis and depression. To investigate the one-year course of anxiety symptoms, every 3 months the following questionnaires are administered until one year after the intervention: Beck Anxiety Inventory (BAI), Fear Questionnaire (FQ), and the State-Trait Anxiety Inventory (STAI-state). To investigate effects of the intervention on quality of life and patient satisfaction, these aspects are assessed at baseline, after the intervention (at 4 months) and at a one-year follow-up in face to face interviews, using respectively the WHODAS and the Quote.

To study predictors of relapse, multiple potential predictors will be assessed at baseline, including social demographics; family history of anxiety and depression (using a pedigree); psychopathology in the past (using life time diagnoses as assessed by the MINI); severity of the last episode; attribution to medication;
treatment history, comorbid psychiatric illnesses (assessed by the MINI, by the Inventory of Depressive Symptoms (IDS), by the Cannabis use self-report and drug use self-report, Alcohol Use Disorders Identification (AUDIT)); physical illnesses; anxiety sensitivity as assessed by the Anxiety Sensitivity Index (ASI); self-esteem as assessed by the Rosenberg Self-esteem Scale, neuroticism as assessed by the Neuroticism scale from the Amsterdamse Biografische Vragenlijst (ABV); mastery as assessed by the Mastery Scale; functioning as assessed by the World Health Organization Disability Assessment Schedule (WHODAS); and reactivity of depressive symptoms using the Leiden Index of Depression Sensitivity (LEIDS).
Discontinuation symptoms will be assessed at each session during the intervention in both conditions, using the Discontinuation Symptom Checklist (DESS). Those predictors that may change due to intervention will also be measured after the intervention, thus at 4 months. To conduct economic analyses, each three months until the one-year follow up health service uptake, work loss and quality of life will be assessed using the Euroqol (EQ-5D), the Trimbos/iMTA questionnaire for costs associated with psychiatric illness (Tic-P) and the modular questionnaire on productivity and disease for economic evaluation studies (PRODISQ).

Intervention

The intervention condition consists of 8 group sessions, each lasting two and a half hours, spread over 4 months. The intervention consists of CBT and discontinuation of AD. The control condition consists of discontinuation of AD as is ususally performed by a psychiatrist in individual visits.

Contacts

Public
A.J. Ernststraat 887
W.D. Scholten

Amsterdam 1081 HL
The Netherlands
+31 (0)20 7884666
Scientific
A.J. Ernststraat 887
W.D. Scholten
Amsterdam 1081 HL
The Netherlands
+31 (0)20 7884666

Eligibility criteria

Inclusion criteria

Included are adults aged 18-65 years, who:

1. Use antidepressants for panic disorder (with or without agoraphobia), social phobia or generalized anxiety disorder;

2. Are in remission;

3. Want to discontinue antidepressant medication.

Exclusion criteria

Patients with 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

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-03-2010
Enrollment:	220
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	18-03-2010
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	NL703
NTR-old	NTR2246
Other	80-82305-97-10009 ZonMw : 2009/318 MEC ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A