Discontinuation of antidepressant medication in primary care whether or not supported by Mindfulness Based Cognitive Therapy (MBCT).

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON42862

Source
ToetsingOnline

Brief title
Discontinuation of antidepressant medication in primary care.

Condition

- Mood disorders and disturbances NEC

Synonym
anxiety, depression

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Innovatiefonds Zorgverzekeraars

Intervention

Keyword: -Antidepressants, -General Practice, -Mindfulness Based Cognitive Therapy (MBCT), -Randomised controlled trial

Outcome measures

Primary outcome

Primary outcome is the proportion of patients successfully discontinuing

antidepressant medication at 6 months (end of treatment).

Secondary outcome

Secondary outcome measures will be the adverse and discontinuation effects,

symptoms of depression and anxiety, psychological well-being, quality of life

and medical and societal costs.

Study description

Background summary

In the Netherlands antidepressants are the most commonly prescribed medication with a total number of users in 2014 of 1.1 million people. After starting antidepressant medication almost 30% of the patients become chronic users. Current NHG-guidelines for primary care advise to discuss discontinuation of antidepressants six months after remission of a depression or 6-12 months after remission of an anxiety disorder. Patients with recurrent depression are advised to discontinue medication after 1-2 years. It is recommended to taper slowly which is defined as a 50% dose reduction every two weeks while monitoring side effects and relapse prevention. Stopping antidepressant medication can be hampered by strong withdrawal effects, which are often difficult to differentiate from early signals of a return of the symptoms of the disorder for which the antidepressants had been described in the first place. Unnecessary treatment can also be caused by anticipation fears of both doctors and patients due to former discontinuation attempts that were unsuccessful. Dutch organizations of depressive and anxious patients such as DV and ADFS notice the need for more guidance in tapering antidepressant medication but are not able to offer their members a clear strategy either.

Considering the fact that a substantial number of patients prefer not to use antidepressant medication given their experience of limited effectiveness and side-effects, there seems to be a need to support them and their attending physicians better in discontinuing it.

Study objective

A first aim of this study is to co-create three types of information material that support the tapering of antidepressant medication: patient documentation, a shared-decision-aid and a discontinuation protocol.
A second aim of this study is to investigate the effectiveness of the combination of a supported protocolized discontinuation (SPD, which includes the decision aid and the discontinuation protocol) and mindfulness-based cognitive therapy (MBCT) in comparison with SPD only in increasing the proportion of patients successfully discontinuing their long-term use of antidepressants in primary care. Secondary outcome measures will be discontinuation effects, symptoms of depression and anxiety, quality of life and medical and societal costs.

Study design

The study consists of two phases.
-Phase 1: Development of materials
Patient documentation, a shared-decision-aid for GPs and a discontinuation protocol.
-Phase 2: Cluster-randomized controlled trial
Patients in primary care using antidepressant medication for more than 9 months will be identified in the electronic prescription system. General practices will be randomly allocated to either Supported Protocolized Discontinuation (SPD) or SPD + Mindfulness Based Cognitive Therapy (MBCT). Patients discontinuing their antidepressant medication are requested to discontinue within 6 months at most. Follow-up assessments take place 6, 9 and 15 months after baseline.

Intervention

General practices offer either SPD or SPD+MBCT
-Supported Protocolized Discontinuation (SPD)
Patient and GP make a shared decision whether to continue of discontinue the antidepressant medication. Those choosing to discontinue will be offered additional meetings with their POH-GGZ to support the discontinuation process.
-SPD + Mindfulness based cognitive therapy (MBCT)
The MBCT is in addition to the SPD. The MBCT-program will be tailored to the needs of patients discontinuing their antidepressant medication. The psycho-educational sections about depression will be accommodated with psycho-education about anxiety, withdrawal effects and pro and cons of stopping

antidepressants.

Study burden and risks

Burden:
-GPs will be asked to identify patients using antidepressant medication for more than 9 months out of their electronic system (HIS) and to invite them to participate in the study. With patients willing to participate they will have a double consultation where the decision aid will be discussed and if applicable a personal taperingschedule will be made.
-The POH-GGZ will be asked to have a minimum of 3 meetings with each patient attending the study to guide and monitor the taperingprocess and follow up.
-Patients participating in the process with SPD will have a double consultation (20 minutes) with their GP to discuss the decision aid and decide whether or not to discontinue. If they discontinue a personal taperingschedule is discussed. After this they will have a minimum of 3 meetings with the POH-GGZ to guide and monitor the taperingprocess and follow up.
-Patients participating in the process with MBCT+SPD will have an additional MBCT training consisting of eight 2,5 hours sessions every two weeks and one silent day of 6 hours
Risk:
Patients may experience withdrawal effects.
Patients may experience a relapse in depression or anxiety.

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

Having received prescriptions for antidepressants in primary care for at least nine months.

Exclusion criteria

1. Current treatment by a psychiatrist;
2. Current diagnosis of substance use disorder;
3. Non-psychiatric indication for long-term antidepressant usage (i.e. neuropathic pain);
4. Inability to perform the necessary assessment due to an understanding of the Dutch language;
5. Cognitive impairments;
6. Younger than 18 years.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	20-02-2017
Enrollment:	138
Type:	Actual

Ethics review

Approved WMO Date:	12-09-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL56937.091.16