INAPPROPRIATE LONG TERM ANTIDEPRESSANT PRESCRIPTION IN GENERAL PRACTICE; cost effectiveness of discontinuation of antidepressant prescribing and patient tailored treatment advice.

Published: 15-12-2009
Last updated: 04-05-2024

This study aims to test the efficiency and cost-effectiveness of a brief collaborative care intervention (primary objective). Assessment of patient wellbeing and (social) functioning are the secondary objectives.

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

Summary

ID

NL-OMON32548

Source
ToetsingOnline

Brief title
INAPPROPRIATE LONG TERM ANTIDEPRESSANT PRESCRIPTION IN GENERAL PRACTICE

Condition

- Mood disorders and disturbances NEC

Synonym
fear, lowered mood

Research involving

Human

Sponsors and support

Primary sponsor: ZonMw
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: antidepressant agents, collaborative and primary care, overtreatment, undertreatment

Outcome measures

Primary outcome

Trial 1: proportion of participants who successfully discontinue their

long-term antidepressants drug use, defined as having no antidepressant drug

use within the last 6 months of the follow-up and the absence of a mood- or

anxiety disorder during one-year follow-up. Trial 2: proportion of participants

in which the mood or anxiety disorders present at baseline, has remitted at

one-year follow-up.

Secondary outcome

Assessment of dimensional measures of psychopathology and in addition direct

and indirect costs.

- the Symptom Checklist 90-item version (SCL-90) for measuring psychological

distress and global psychopathology

- the Centre for Epidemiological Studies Depression Scale (CES-D) for

measuring depressive symptoms

- the Penn State Worry Questionnaire (PSWQ) for assessing the frequency and

severity of symptoms of worrying

- the Panic and Agoraphobic Scale (PAS) for measuring the severity of illness in patients with panic disorder

- the Fear of Negative Evaluation Scale (FNES) for assessing expectations and distress associated with negative evaluations by others

- the EuroQol-5D (EQ-5D) will be included as a utility instrument enabling the economic analyses. The EQ-5D has previously been validated and has been applied successfully in studies of mood- and anxiety disorder;

- Costs will be measured by the Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness (TiC-P)

- and the DESS scale will be used to assess the prevalence of the AD discontinuation syndrome.

- Demographic variables (including ethnic origin) and the use of psycho-active substances (nicotine, alcohol, drugs) will be recorded at the baseline interview.

- Personality characteristics and the patient-physician relationship will be examined by administration of the NEO-Five Factor Inventory (NEO-FFI) and the Patient-centeredness questionnaire, respectively.

- The number of comorbid chronic somatic disorders will be assessed at baseline using the EMD of the GP.

Study description

Background summary

Inappropriate prescription of antidepressants is worrisome for reasons of patient safety and costs in case of overtreatment (continuation in the absence

of a clinical indication) and, in case of undertreatment (continuation in the absence of therapeutic efficacy), because of disorder-related burden, i.e. lack of wellbeing and associated costs. Both scenarios are highly prevalent according to a recent Dutch report, and applicable to approximately half of all long term AD users (50-60 long-term users of antidepressants per average Dutch general practice).

Study objective

This study aims to test the efficiency and cost-effectiveness of a brief collaborative care intervention (primary objective). Assessment of patient wellbeing and (social) functioning are the secondary objectives.

Study design

Two randomised, controlled parallel-group trials will be conducted in tandem. The choice for two trials is inherent to the aim of the study, i.e. reduction of inappropriate antidepressant usage, which could be based on the absence of a clinical indication (trial 1) and on the absence of therapeutic efficacy (trial 2), respectively. Cluster randomization will be used at the level of general practices (intervention arm in trial 1 and 2 vs usual care in trial 1 and 2).

Intervention

Based on a structured psychiatric interview the GPs will receive a tailor made treatment proposal based on the Dutch multidisciplinary guideline on mood- and anxiety disorders. Patients receiving antidepressants outside a valid clinical indication will be randomised to receive a discontinuation intervention or treatment as usual (trial 1, equivalence trial). Patients receiving antidepressants but still suffer from a psychiatric disorder will be randomised to receive a patient-tailored treatment proposal based on current multidisciplinary guidelines for the treatment of depressive or anxiety disorders or treatment as usual (trial 2, superiority trial). This advice is a patient-tailored treatment given to the GP in case of a psychiatric disorder despite long-term antidepressant usage.

Study burden and risks

The control conditions for both trials consist of usual care and do not impose restrictions on GPs to deliver care or to refer to specialised mental health care, including the continuation or discontinuation of psychotropic drugs. Therefore the control patients do not pose any risks. The intervention is according to Dutch guidelines, thus no risk is to be expected.

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

9 or more months of using antidepressants

Exclusion criteria

a) current treatment in a psychiatric setting;
b) history of psychosis, bipolar disorder, or obsessive compulsive disorder;
c) addiction;
d) recurrent depression with 3 or more episodes;
e) recurrent disorders with at least two relapses after antidepressant-discontinuation.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2010
Enrollment:	480
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	15-12-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-06-2012
Application type:	Amendment
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	NL29718.091.09