Prescribing Anti Depressant Appropriately.

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25490

Bron
NTR

Verkorte titel
PANDA study

Aandoening

inappropriate long term anitedepressant use
cost effectiveness
collaborative care
depression
doelmatigheid
antidepressiva
kosten effectiviteit
depressie

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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 found at baseline, has remitted at one-year follow-up.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
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, showing a prevalence rate of 50-60 long-term users of antidepressants per average Dutch general practice (2350 patients).

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 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).

Study population:
Long-term antidepressant users (> 9 months) in general practice will be identified by performing a computerised search for prescriptions of antidepressants based on unique

medication codes within the electronic medical dossier.

Intervention:
Based on a structured psychiatric interview the GPs 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 next treatment proposal based on current guidelines or treatment as usual (trial 2, superiority trial). This advice can be discontinuation (in case of absence of a psychiatric disorder) as well as a patient-tailored treatment advice given to the GP in case of a psychiatric disorder despite long-term antidepressant usage.

Main study parameters/endpoints:
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 found at baseline, has remitted at one-year follow-up.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
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.

Doel van het onderzoek

This study aims to test the efficiency and cost-effectiveness of a brief collaborative care intervention, in long-term users (>9months) of antidepressants in the general practice. This intervention will contain a patient-tailored treatment proposal according to current guidelines based on the outcome of a structured psychiatric interview.
The hypothesis is that this intervention will reduce the inappropriate long term antidepressant prescription in general practice. In the case of overtreatment we hypothesize that this intervention will reduce the use of antidepressants and in the case of undertreatment that the intervention will result in remission of the psychiatric disorder.

Onderzoeksopzet

0 months, secondary outcome measures at 3,6,9 months and endpoint at 12 months.

Onderzoeksproduct en/of interventie

Trial 1:

The active intervention in trial 1 (absence of indication for antidepressant drugs) implies the discontinuation of antidepressant use, following the recommendations in the Dutch multidisciplinary guidelines for mood- and anxiety disorders [2, 3]. These are similar to those in the British NICE guidelines, recommending strict indications for the initiation and continuation of antidepressants [15]. A recent meta-analysis patients showed no difference in relapse rates between abrupt and gradual antidepressant discontinuation in patients with a single depressive episode [31]. In patients who suffered from an anxiety disorder or a recurrent depressive disorder at the time of initiating the antidepressant, abrupt discontinuation of antidepressants might induce a relapse [31]. Termination of antidepressant use may cause discontinuation symptoms. Estimates of the prevalence of the SSRI/TCA discontinuation syndrome vary widely [32, 33]. Discontinuation symptoms occur more frequently in patients who abruptly discontinue their antidepressants than in patients whose treatment is gradually tapered [33]. Therefore we will advise to gradually taper the antidepressant use over the course of several weeks. The GP will receive an information sheet with current guidelines on antidepressant tapering and the discontinuation syndrome. No treatment restrictions are imposed on GP or patient in case of relapse or onset of a new psychiatric disorder after discontinuation.

Trial 2:

The active intervention of trial 2 (presence of psychiatric disorder despite antidepressant drug use) consists of disclosure of the psychiatric diagnosis found with the CIDI and disclosure of the treatment history. The GP and the patient will receive a patient-tailored treatment proposal based on current treatment guidelines. The efficaciousness of this intervention is supported by systematic reviews and meta-analyses regarding the improvement of quality of care for patients with mood- or anxiety disorders [17-20, 34]. The treatment proposal is based on the Dutch Multidisciplinary Guidelines for the treatment of depressive disorder and of anxiety disorders [2, 3]. These Multidisciplinary Guidelines provide detailed information and a treatment algorithm for all mood- and anxiety disorders. All treatment proposals will be made up independently by an experienced GP (EvR) and a psychiatrist (RCOV). They will be discussed weekly with two senior research clinicians (AEMS/JS and PL) and result in a final treatment proposal for the GP. Non-congruence between EvR and RCOV will be reported as percentage disagreement. If the treatment algorithm suggests two or three options, all possible treatment options will be described in detail. The algorithms for the preparation of the treatment advice will be based on up-to-date versions of the Multidisciplinary Guidelines Depression and Anxiety [2, 3].

In summary, the basic algorithm for patients treated with antidepressant drugs for over 9 months include:
(1) if a depressive disorder is still present: (a) optimising current treatment (i.e. adjustment of

dosage, psycho-education to improve compliance, more strict adherence to psychotherapy protocols), (b) medication switch (mostly an antidepressant of another class), (c) referral to a psychologist for cognitive behavioural therapy or interpersonal psychotherapy, (d) referral to secondary care.
(2) if an anxiety disorder is still present (a) optimising current treatment (see above), (b) referral to a psychologist for a disease-specific, protocol-based cognitive-behavioural therapy, (c) medication switch, and (d) referral to secondary care.

The treatment proposal will not be based merely on the diagnosis but will be tailored, explicitly taking into account treatment compliance, symptom severity, course of the disorder, and treatment history. In this way, patient safety is guaranteed. The GP is given written advice to optimise ongoing treatment according to current guidelines.

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. Since baseline psychiatric diagnostics will not be disclosed, we expect continuation of antidepressant drug treatment in most cases [7].

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Long-term use of antidepressants is defined as receiving antidepressant prescriptions for at least nine months with a prescribed amount sufficient for at least 180 days of consumption in accordance with the recommended dosage.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Current treatment in a psychiatric setting;

2. History of psychosis, bipolar disorder, or obsessive compulsive disorder;

3. Addiction;

4. Recurrent depression with 3 or more episodes;

5. Recurrent disorders with at least two relapses after antidepressant-discontinuation.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	12-01-2009

Aantal proefpersonen:	360
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1915
NTR-old	NTR2032
Ander register	ZonMW : 80-82310-98-09062
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A