

Mild depression in primary care: do antidepressants add any effect to usual consultations?

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Antidepressant medication does not add any effect to usual consultations by general practitioners in patients with minor and mild-major depression.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20223

Bron

NTR

Verkorte titel

HOMiD

Aandoening

Depression.

Ondersteuning

Primaire sponsor: VU University Medical Centre

EMGO-Institute

Dept. General Practice

Overige ondersteuning: College voor Zorgverzekeringen.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Severity of Depressive by MADRS (Montgomery Åsberg Depression Rating Scale);

2. Remission of depression by MADRS score<10.

Toelichting onderzoek

Achtergrond van het onderzoek

Objective:

To examine whether antidepressant medication adds any effect to usual consultations by the General Practitioner (GP) in adult patients with minor and mild-major depression.

Design:

A pragmatic patient-randomised equivalence trial with 12 months follow up.

Setting:

59 GPs in The Netherlands recruited eligible patients.

Participants:

181 contacting patients entered the study with minor or mild-major depression. Mean age was 46 years (SD 16.0) and 73% were female. Complete follow up on the primary outcomes was available for 131 patients (72%).

Interventions:

Patients were randomly assigned to on average 3 usual consultations during 3 months with (n=85) or without paroxetine (n=96). Both treatments were carried out by the patient's own GP.

Main outcome measure:

Depression severity by the Montgomery Åsberg Depression Rating Scale and remission from depression at 6, 13, 26 and 52 weeks follow up. Secondary outcome measures were the Short Form 36, Beck Depression Inventory and Client Satisfaction Questionnaire.

Results:

The intention-to-treat analysis showed that paroxetine with counselling was equivalent (i.e. non-superior) to counselling alone at 6, 13 and 52 weeks, but not at 26 weeks. The power was too low to draw firm conclusions on the per-protocol analysis. Patients who received usual consultations were at least as satisfied with their treatment as patients receiving additional antidepressives. Non-inferiority of costs could be demonstrated for 76% of the cases.

Conclusion:

Apparently, paroxetine does not add to the treatment effect of usual consultations by GPs in patients with minor and mild-major depression.

Doel van het onderzoek

Antidepressant medication does not add any effect to usual consultations by general practitioners in patients with minor and mild-major depression.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Patients were randomly assigned to four sessions of counselling during 3 months with (n=85) or without paroxetine (n=96). Both treatments were carried out by the patient's own GP.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Aged 18 years or over;
2. Having 3-6 out of 9 depressive symptoms for at least 2 weeks for most days of the week, including at least one of the core symptoms 'sadness' or 'loss of pleasure';
3. Impairment by depressive symptoms in social, occupational or other important areas of functioning. (minor depression=3-4 symptoms, mild-major depression=5-6 symptoms).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Current intake of antidepressants or receiving psychological therapy;
 2. Psychotic features;
 3. Alcohol or drug addiction;
- Z

4. Loss of a loved one or significant other in the past six months;
5. Pregnancy or breastfeeding;
6. Inability to complete questionnaires because of language difficulties, illiteracy or cognitive decline;
7. Not having a telephone.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2002
Aantal proefpersonen:	181
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	02-09-2005
Soort:	Eerste indiening

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	NL143
NTR-old	NTR178
Ander register	: OOG00-020
ISRCTN	ISRCTN03007807

Resultaten

Samenvatting resultaten

BMC Med. 2007 Dec 7;5:36.