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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20223

Source
NTR

Brief title
HOMiD

Health condition

Depression.

Sponsors and support

Primary sponsor: VU University Medical Centre
EMGO-Institute
Dept. General Practice
Source(s) of monetary or material Support: College voor Zorgverzekeringen.

Intervention

Outcome measures

Primary outcome

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

2. Remission of depression by MADRS score<10.

Secondary outcome

1. Quality of Live (Short Form 36);

2. Subjective deprssion (Beck Depr. Inventory);

3. Client Satisfaction Questionnaire;

4. Direct and indirect costs.

Study description

Background summary

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.

Study objective

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

Study design

N/A

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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).

Exclusion criteria

1. Current intake of antidepressants or receiving psychological therapy;

2. Psychotic features;

3. Alcohol or drug addiction;
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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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2002
Enrollment:	181
Type:	Actual

Ethics review

Positive opinion

Date:	02-09-2005
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	NL143
NTR-old	NTR178
Other	: OOG00-020
ISRCTN	ISRCTN03007807

Study results

Summary results
BMC Med. 2007 Dec 7;5:36.