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

Submission date	Recruitment status
20/12/2005	No longer recruiting
Registration date	**Overall study status**
20/12/2005	Completed
Last Edited	**Condition category**
06/07/2009	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR178; OOG00-020

Study information

Scientific Title

Acronym
HOMiD

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Multicentre, randomised, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Depression

Interventions
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 patients own GP.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

paroxetine

Primary outcome measure
1. Severity of Depressive by MADRS (Montgomery Åsberg Depression Rating Scale)
2. Remission of depression by MADRS score<10

Secondary outcome measures
1. Quality of Live (Short Form 36)
2. Subjective depression (Beck Depression. Inventory)
3. Client Satisfaction Questionnaire
4. Direct and indirect costs

Overall study start date
01/01/2002

Completion date
01/05/2005

Eligibility

Key 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. Impairment by depressive symptoms in social, occupational or other important areas of functioning (minor depression=3-4 symptoms, mild-major depression=5-6 symptoms)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
181

Key exclusion criteria
1. Current intake of antidepressants or receiving psychological therapy
2. Psychotic features
3. Alcohol or drug addiction
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

Date of first enrolment
01/01/2002

Date of final enrolment
01/05/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
VU University Medical Centre,
Amsterdam
Netherlands
1081 BT

Sponsor information

Organisation
EMGO Institute (Netherlands)

Sponsor details
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Sponsor type
Not defined

ROR
https://ror.org/0258apj61

Funder(s)

Funder type

Government

Funder Name
The Health Care Insurance Board (CVZ) (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	07/12/2007		Yes	No