

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

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/07/2009	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Hein Hout, van

Contact details

VU University Medical Centre,
EMGO-Institute,
Department of General Practice,
Van der Boechorststraat 7
Amsterdam
Netherlands
1081 BT

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

Van der Boechorststraat 7

Amsterdam

Netherlands

1081 BT

+31 20 4448180

emgo@vumc.nl

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