Short-term cognitive behavioural therapy and short-term psychoanalytical supportive psychotherapy as treatment for depression: a randomised clinical trial

Submission date	Recruitment status No longer recruiting	Prospectively registered		
28/12/2006		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
28/12/2006	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
04/11/2013	Nervous System Diseases			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Acronym

Praten & Pillen V

Study objectives

A randomised clinical trial comparing the efficacy, efficiency and applicability of short-term cognitive behavioural therapy and short-term psychoanalytical supportive psychotherapy in the treatment of depressive disorders.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Dutch council of medical-ethic boards for mental health institutes (Stichting Medisch-Etische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg [METiGG]) on the 12th May 2006 (ref: 5236).

Study design

Randomised, parallel group, multicentre trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Depressive disorders

Interventions

1. Mild to moderate depression (HDRS score 14 to 24):

Short-term Cognitive Behavioral Therapy or Short-term Psychoanalytical Supportive Psychotherapy. 16 sessions of 45 minutes, during 22 weeks.

2. Severe depressive symptoms (HDRS score more than 24):

Combination treatment: psychotherapy as mentioned above in combination with antidepressants.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Depressive complaints according to patient, therapist and independent rater at week 5, 10, 22 and 52.

Secondary outcome measures

- 1. Quality of life
- 2. Predictors of treatment outcome at week 22 and 52

Overall study start date

01/04/2006

Completion date

01/07/2009

Eligibility

Key inclusion criteria

- 1. Main diagnosis of:
- a. Major Depressive Episode
- b. Major Depressive Disorder
- c. Depressive Disorder not otherwise specified according to Diagnostic and Statistical Manual of Mental Disorders Fourth Edition (DSM-IV) criteria
- 2. Hamilton Depression Rating Scale (HDRS) score more than 14
- 3. Age 18 to 65
- 4. Written informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

300

Key exclusion criteria

- 1. Bipolar Disorder
- 2. Depressive disorder with psychotic features

- 3. Suicide risk
- 4. Loss of impulse-control
- 5. Use of non-trial anti-depressants
- 6. Use of anti-psychotics or mood stabilisers
- 7. Substance abuse
- 8. Language problems
- 9. Contact with same Mentrum location within last six months

Date of first enrolment

01/04/2006

Date of final enrolment

01/07/2009

Locations

Countries of recruitment

Netherlands

Study participating centre

Klaprozenweg 111

Amsterdam Netherlands 1033 NN

Sponsor information

Organisation

Mentrum Mental Health Care Amsterdam (The Netherlands)

Sponsor details

P.O. Box 75848 Amsterdam Netherlands 1070 AV

Sponsor type

Research organisation

Website

http://www.mentrum.nl/

Funder(s)

Funder type

Industry

Funder Name

Wyeth Pharmaceuticals (The Netherlands) - unrestricted grant

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	01/09/2013		Yes	No