ISRCTN31263312 https://doi.org/10.1186/ISRCTN31263312

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

Submission date
28/12/2006

Recruitment status
No longer recruiting

Registration date
28/12/2006

Overall study status
Completed

Last Edited
04/11/2013

Condition category
Nervous System Diseases

[_] 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

N/A

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