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Psychotherapy for residual depression following initial treatment: effectiveness, relapse prevention and mechanisms of change

Submission date
16/01/2007

Recruitment status
No longer recruiting

Registration date
16/01/2007

Overall study status
Completed

Last Edited
22/11/2011

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.stepd.nl

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
STEP-D

Study objectives
Are Cognitive Behavioural Therapy (CBT) and InterPersonal Therapy (IPT) following initial treatment effective interventions that prevent relapse of recurrence of depression in the long-term? What are the mechanisms of change in CBT and IPT?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the local ethics committee (Medisch Ethische Commissie azM/UM) on the 5th December 2006 (ref: MEC 06-3-063).

Study design
Randomised, controlled, parallel group 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
Depression

Interventions
1. Cognitive Behaviour Therapy (CBT), N=75
2. InterPersonal Therapy (IPT), N=75
3. Eight-week waiting list, N=30

CBT= max. 20 sessions
IPT= max. 20 sessions

All interventions are delivered by qualified therapists under supervision at the Academic Riagg Maastricht.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Depressive relapse/recurrence in the course of 24 months.

Secondary outcome measures
1. Severity of depression (BDI)
2. Psychological problems
3. Health care consumption
4. Explicit and implicit mechanism of change measures

Overall study start date
01/08/2006

Completion date
01/08/2011

Eligibility

Key inclusion criteria
1. One or more episodes of Major Depressive Disorder (MDD) in past two years
2. Initial treatment for depressive symptoms
3. Residual symptoms of depression (Beck Depression Inventory [BDI] more than or equal to ten)

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
180

Key exclusion criteria
1. Chronic depression
2. Concurrent treatment for depression
3. Severe co-morbidity
4. Medical conditions that explain depressive symptoms

Date of first enrolment
01/08/2006

Date of final enrolment
01/08/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
University Maastricht (UM)
Maastricht
Netherlands
6200 MD

Sponsor information

Organisation
University Maastricht (UM) (The Netherlands)

Sponsor details
Department of Medical Clinical and Experimental Psychology (DMKEP)
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Maastricht
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6200 MD

Sponsor type
University/education

Website
http://www.unimaas.nl/default.asp?taal=en

ROR
https://ror.org/02jz4aj89

Funder(s)

Funder type
University/education

Funder Name
University Maastricht (UM) (The 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?
Protocol article	protocol	14/06/2011		Yes	No