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Stepped care in Depression and Anxiety: from primary to secondary care

Submission date	Recruitment status	[X] Prospectively registered
28/12/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/12/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/11/2011	Mental and Behavioural Disorders	

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
SAD

Study objectives
A stepped care program in primary care for patients with depressive and/or anxiety disorders is more effective than care as usual.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Medical Ethics Review Committee of the VU Medical Centre on the 1st February 2007 (ref: 06/248).

Study design
Randomised, controlled, 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, Anxiety disorders

Interventions
In the current study a stepped care program will be developed for primary care patients with anxiety and/or depression. A stepped care program is characterised by different steps of treatment that are arranged in order of increasing intensity. After each step, the patient will be monitored, to determine if symptoms have been sufficiently reduced. The program consists of evidence based interventions: 1. Watchful waiting
2. Bibliotherapy
3. Problem solving treatment
4. Medication and/or an evidence based treatment in specialised mental health care

The control condition is care as usual.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Speed of recovery in terms of symptom reduction (Quick Inventory of Depressive Symptomatology [QIDS] for depression, and the Hospital Anxiety and Depression Scale [HADS-A] for anxiety) at baseline and after eight, 16 and 24 weeks.

Secondary outcome measures
At baseline and after eight, 16 and 24 weeks:
1. DSM diagnosis (Composite International Diagnostic Interview [CIDI])
2. Quality of life (Short Form health survey [SF36] and Euroqol questionnaire)
3. The use of health care services (Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness [TIC-P])
4. The use of medication (TIC-P)
5. Productivity losses (TIC-P)
6. Satisfaction with delivered care/continuity of care (Quote)

Overall study start date
01/01/2007

Completion date
01/09/2010

Eligibility

Key inclusion criteria
They are recruited through screening (all patients who visited their General Practitioner [GP]). They have to meet the following criteria:
1. Between 18 to 65 years
2. A Diagnostic and Statistical Manual of mental disorders (DSM) diagnosis of minor depression, major depression, dysthymia, panic disorder (with or without agoraphobia), generalised anxiety disorder, or social phobia. Patients with minor anxiety (not fulfilling any DSM criteria of an anxiety disorder) will also be included

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
200

Key exclusion criteria
1. Have psychotic or bipolar symptoms
2. Have a high suicide risk
3. Are currently under treatment or received treatment for depression/anxiety in the past twelve months
4. Cannot read or write Dutch sufficiently enough to complete the questionnaires

Date of first enrolment
01/01/2007

Date of final enrolment
01/09/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
VU University Medical Center, FPP
Amsterdam
Netherlands
1081 BT

Sponsor information

Organisation
VU University Medical Center (The Netherlands)

Sponsor details
EMGO Institute
Van der Boechorststraat 7
Amsterdam
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1081 BT
+31 (0)20 444 8180
emgo@vumc.nl

Sponsor type
Hospital/treatment centre

Website

http://www.vumc.nl/

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (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?
Results article	results	07/07/2011		Yes	No