

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

Submission date 28/12/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/12/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 22/11/2011	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Laura Kool

Contact details
VU University Medical Center, FPP
Department of Clinical Psychology
Van der Boechorststraat 1
Amsterdam
Netherlands
1081 BT
+31 (0) 20 598 2544
lm.kool@psy.vu.nl

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
Netherlands
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