Cognitive behaviour therapy versus selfexamination therapy with depressive symptomatology

Submission date	Recruitment status No longer recruiting	Prospectively registered		
28/12/2006		[X] Protocol		
Registration date 28/12/2006	Overall study status Completed Condition category	Statistical analysis plan		
		[X] Results		
Last Edited		[] Individual participant data		
21/04/2011	Mental and Behavioural Disorders			

Plain English summary of protocol

Not provided at time of registration

Study website

http://www.psy.vu.nl/depressiviteitondercontrole

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

NTR804

Study information

Scientific Title

Acronym

DOC

Study objectives

Cognitive behaviour therapy and self-examination therapy are both more effective in reducing depressive complaints than a waiting list control group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local ethics committee (Medisch Ethische Toetingscommissie of the VUMC) on the 7th September 2007 (ref: 2006/168).

Study design

Randomised, parallel group, controlled 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 symptoms

Interventions

The cognitive-behavioural intervention is called Color your life (Kleur je leven). This intervention consists of eight lessons (one lesson a week). Four weeks later, the ninth lesson takes place. The intervention focuses on increasing pleasurable activities, increasing social skills and decreasing dysfunctional cognitions.

Self examination therapy is based on problem solving therapy. We use the Dutch version, called 'Alles onder controle'. This intervention takes five weeks. During this intervention participants determine what matters to them, think less negatively about things that do not matter to them, invest their energy in things that are important to them (by using problem-solving strategies) and accept situations they cannot change.

Both interventions are computer-based.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Depressive symptom level will be measured with the Center for Epidemiological Studies Depression Scale (CES-D).

Secondary outcome measures

- 1. Quality of life is measured by the Eurogol Questionnaire
- 2. Anxiety symptoms are measured by the anxiety subscale of the Hospital Anxiety and Depression Scale (HADS)
- 3. Dysfunctional cognitions are measured by the Dysfunctional Attitude Scale (DAS)
- 4. Worrying is measured by the Penn State Worry Questionnaire (PSWQ)
- 5. Problem solving skills are measured by the Social Problem Solving Skills-Revised (SPSI-R)
- 6. Mastery is measured by the Mastery Scale
- 7. Absence at work and use of healthcare are measured by the Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness (TIC-P)

Overall study start date

01/10/2006

Completion date

01/10/2007

Eligibility

Key inclusion criteria

Score of 16 or higher on the Center for Epidemiological Studies Depression scale (CES-D).

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Key exclusion criteria

Does not comply with the above inclusion criteria

Date of first enrolment

01/10/2006

Date of final enrolment

01/10/2007

Locations

Countries of recruitment

Netherlands

Study participating centre VU University Medical Center, FPP

Amsterdam Netherlands 1081 BT

Sponsor information

Organisation

Vrije University Medical Centre (VUMC) (The Netherlands)

Sponsor details

Department of Clinical Psychology Van der Boechorststraat 1 Amsterdam Netherlands 1081 BT

Sponsor type

Hospital/treatment centre

Website

http://www.vumc.nl/

ROR

https://ror.org/00q6h8f30

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Vrije University Medical Centre (VUMC) (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?
<u>Protocol article</u>	protocol	19/12/2007		Yes	No
Results article	results	19/12/2010		Yes	No