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Cognitive behaviour therapy versus self-examination therapy with depressive symptomatology

Submission date	Recruitment status
28/12/2006	No longer recruiting
Registration date	**Overall study status**
28/12/2006	Completed
Last Edited	**Condition category**
21/04/2011	Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

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

Contact information

Type(s)
Scientific

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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 Euroqol 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

300

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?
Protocol article	protocol	19/12/2007		Yes	No
Results article	results	19/12/2010		Yes	No