ISRCTN68246470 https://doi.org/10.1186/ISRCTN68246470

(Cost)effectiveness of a cognitive group prevention module for recurrent depression

Submission date	Recruitment status	[ ] Prospectively registered
27/01/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/01/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/11/2015	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Claudi Bockting

Contact details
Academic Medical Center
De Meren
Tafelbergweg 25 P2-221
Amsterdam
Netherlands
1105 BC
-
c.l.bockting@amc.uva.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
(Cost)effectiveness of a cognitive group prevention module for recurrent depression

Study objectives
Our primary hypothesis was that in remitted patients with recurrent depression, augmenting treatment as usual (TAU) with cognitive therapy (CT) would reduce and/or postpone relapse /recurrence. In view of Teasdale's findings (et al., 2000), we expected this effect to be moderated by the number of previously experienced depressed episodes. As secondary hypotheses, we expected that augmenting treatment as usual with CT would also reduce the severity of a depressive episode, and the number of times a patient would have a relapse /recurrence. Finally, an exploratory aim of the study was to analyze differences in demographic, clinical and psychological characteristics between patients below or above the reversal point for number of previous depressive episodes needed for potential benefit from CT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Multicentre randomised single-blind active-controlled parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Depression

Interventions
Cognitive therapy (CT). The CT in the experimental condition involved eight weekly two-hour sessions. As in other prevention studies (Ma & Teasdale, 2004; Teasdale et al., 2000) a group format was chosen, for cost-effectiveness reasons but also because we were dealing with a patient group without current psychopathology. More specifically, we used a closed format with a mean membership of 8 (7 to 12 members). Each CT session followed a fixed structure, with

agenda setting, review of homework, explanation of rationale of each session, and assignment of homework. Nine specifically trained psychologists (one of them was the principal investigator) delivered the prevention module; all were fully trained cognitive behavior therapists (minimum of 5 years of training). Before conducting the experimental groups, each therapist received 16 hours of additional specific training. A treatment manual (available on request from first author) was used and regular supervision was provided. All intervention group sessions were audiotaped to enable treatment integrity to be evaluated, using a checklist of all particular interventions. Any adherence or competence issues were resolved with the therapist prior to the subsequent session (in fact only one instance: an overlooked homework assignment). The CT was focused mainly on identification and change of dysfunctional attitudes. Unlike CT for acutely depressed patients (Beck, 1987; Beck, Rush, Shaw, & Emery, 1979), the present module was not primarily directed toward modifying negative thoughts. Instead, it started with the identification of negative thoughts (Session 1) and dysfunctional attitudes, aided by a self report questionnaire with examples of attitudes and techniques such as vertical arrow technique (Sessions 1-3), and then proceeded to focus on changing of these attitudes using different cognitive techniques such as Socratic questioning and identification of positive attitudes (Sessions 3-7). Moreover, patients were encouraged to practice with alternative attitudes (Sessions 6-8). In contrast with the preventive program of Teasdale and colleagues (2000), involving additional meditation interventions were used, solely cognitive interventions were used in the present study, concentrated on change of content. Several studies have found that in comparison with normal controls acutely depressed patients have a tendency to retrieve more overgeneral autobiographical memories on a cue-word task (i.e. more generic memories of past events rather than specific memories referring to a particular event happening on a particular time and place [Goddard, Dritschel & Burton, 1996; Williams & Scott, 1988]). This inability to retrieve specific memories from the past is associated with impaired problem-solving skills (Pollock & Williams, 2001), long-term course of depressive disorders (Peeters, Wessel, Merkelbach, & Boon-Vermeeren, 2002) and difficulties in recovering from depression (Brittlebank, Scott, Williams, & Ferrier, 1993). Unlike with traditional acute CT, patients were asked to keep a diary of positive experiences in order to enhance specific memories of positive experiences, instead of retaining overgeneral memories. (sessions 4-6). Further specific relapse /recurrence prevention strategies were formulated in the last three sessions.
Control group: treatment as usual

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Relapse/recurrence: To assess relapse/recurrence, we used the Structured Clinical Interview for DSM-IV (SCID-I; First, Gibbon, Spitzer, & Williams, 1996). At baseline and at three follow-up assessments (3, 12, and 24 months), current and past depressive episodes were checked.

Secondary outcome measures
The number of relapse/recurrence and severity of relapse/recurrence

Overall study start date
01/09/1999

Completion date

31/12/2005

Eligibility

Key inclusion criteria
1. Experienced at least two Major Depressive Episodes (MDEs) in the previous five years, as defined according to the Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV: American Psychiatric Association, 1994) and assessed with the Structured Clinical Interview for DSM-IV (SCID; First, Gibbon, Spitzer, & Williams, 1996) administered by trained interviewers
2. Were currently in remission according to DSM-IV criteria, for longer than ten weeks and no longer than two years (i.e. a high-risk group of relapse/recurrence)
3. Obtained a current score of <10 on the Hamilton Rating Scale for Depression (Hamilton, 1960)

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
187

Key exclusion criteria
1. Current mania or hypomania or a history of bipolar illness
2. Any psychotic disorder (current and previous)
3. Organic brain damage
4. Alcohol or drug misuse
5. Predominant anxiety disorder
6. Recent ECT
7. Recent cognitive treatment or receiving CT at the start of the study, or current psychotherapy with a frequency of more than two times a month

Date of first enrolment
01/09/1999

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
Netherlands

Study participating centre

Academic Medical Center
Amsterdam
Netherlands
1105 BC

Sponsor information

Organisation
Academic Medical Centre (Netherlands)

Sponsor details
De Meren
Tafelbergweg 25
Amsterdam
Netherlands
1105 BC

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Research organisation

Funder Name
National Foundation of Mental Health Care (Nationaal Fonds Geestelijke Volksgezondheid [NFGV]) (Netherlands)

Funder Name
Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location
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	01/08/2005		Yes	No
Results article	results	01/08/2010		Yes	No
Results article	results	01/08/2012		Yes	No
Results article	results	01/06/2013		Yes	No
Results article	results	01/09/2015		Yes	No
Results article	results	01/10/2015		Yes	No