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Rumination-Focused Cognitive Behavioural Therapy for residual depression

Submission date	Recruitment status
11/03/2011	No longer recruiting
Registration date	**Overall study status**
15/04/2011	Completed
Last Edited	**Condition category**
15/04/2011	Mental and Behavioural Disorders

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

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
Rumination-Focused Cognitive Behavioural Therapy for residual depression: a pilot randomised controlled trial

Acronym
RFCBT

Study objectives
The addition of rumination-focused CBT to standard clinical management and antidepressant medication (CM + ADM) for residual depression will produce significantly greater reduction in rumination and symptoms of depression than CM + ADM alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North and East Devon REC approved on 18th November 2003 (REC ref no : 2003/11/222)

Study design
Multi-site randomised controlled adjunctive trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Residual treatment-resistant depression

Interventions
Intervention: Rumination-focused cognitive-behavioural therapy (RFCBT) as ajdunct to treatment-as-usual. RFCBT is a manualised CBT treatment, consisting of up to 12 individual 60 minute sessions scheduled weekly or fortnightly. RFCBT is theoretically informed by experimental research indicating that there are distinct constructive and unconstructive forms of rumination.It is designed to coach patients to shift from unconstructive rumination to

constructive rumination, through the use of functional analysis, experiential/imagery exercises and behavioural experiments. As such, RFCBT incorporates the functional-analytic and contextual principles and techniques of Behavioural Activation (BA), but focused on rumination

Control: treatment-as-usual (TAU). TAU consisted of ongoing maintenance antidepressant medication and outpatient clinical management across the same 5 months time period of the combined treatment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Hamilton Rating Scale for Depression (HRSD)
2. Beck Depression Inventory (BDI-II)

Secondary outcome measures
1. The Structured Clinical Interview for DSM-IV (SCID) to assess diagnostic status for major depression
2. Ruminative Response Scale of the Response Styles Questionnaire (RRS) to assess rumination

Overall study start date
01/09/2004

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Aged >18
2. Meeting criteria for medication-refractory residual depression defined as:
2.1. Meeting Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) criteria for major depression within the last 18 months but not in the last 2 months
2.2. Residual symptoms reaching at least 8 on the 17-item Hamilton Depression Rating Scale (HRSD) and 9 on the Beck Depression Inventory (BDI-II)
2.3. Taking antidepressant medication at a therapeutic dose as recommended by the British National Formulary and/or equivalent to 125mg of amitriptyline for at least 8 weeks continuously during the current episode and within the last 2 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
42

Key exclusion criteria
1. A history of bipolar disorder, psychosis
2. Current drug or alcohol dependence
3. Learning disability
4. Organic brain damage
5. Concurrent psychotherapy at point of entry to the study

There were no exclusion criteria with respect to co-morbid anxiety disorders or Axis II diagnosis

Date of first enrolment
01/09/2004

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Mood Disorders Centre
Exeter
United Kingdom
EX4 4QG

Sponsor information

Organisation
University of Exeter (UK)

Sponsor details
Research & Knowledge Transfer
University of Exeter (Streatham Campus)
Innovation Centre Phase 2
Rennes Drive
Devon

Exeter
England
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Sponsor type
University/education

Website
http://www.exeter.ac.uk

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Charity

Funder Name
NARSAD (National Alliance for Research into Schizophrenia and Depression) (USA)

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	01/09/2007		Yes	No