

# Rumination-Focused Cognitive Behavioural Therapy for residual depression

<b>Submission date</b> 11/03/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 15/04/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 15/04/2011	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

**Protocol serial number**  
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

**Study type(s)**

Treatment

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

Residual treatment-resistant depression

**Interventions**

Intervention: Rumination-focused cognitive-behavioural therapy (RFCBT) as adjunct 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(s)**

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

## **Key secondary outcome(s)**

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

## **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **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

United Kingdom

England

## Study participating centre

### Mood Disorders Centre

Exeter

United Kingdom

EX4 4QG

# Sponsor information

## Organisation

University of Exeter (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

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details results	Date created	Date added	Peer reviewed?	Patient-facing?
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[Results article](#)

01/09/2007

Yes

No