

# Preventing depressive relapse/recurrence in NHS settings through mindfulness-based cognitive therapy (MBCT)

<b>Submission date</b> 28/04/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 07/05/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/11/2024	<b>Condition category</b> Mental and Behavioural Disorders	<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

**EudraCT/CTIS number**  
2009-012428-10

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

HTA 08/56/01; MBCT2009

## **Study information**

### **Scientific Title**

Preventing depressive relapse/recurrence in NHS settings through mindfulness-based cognitive therapy (MBCT): a randomised controlled trial

### **Acronym**

MBCT

### **Study objectives**

The pragmatic aim of the proposed trial is to establish whether Mindfulness-based Cognitive Therapy (MBCT) provides an effective alternative relapse prevention approach to maintenance anti-depressant medication (m-ADM) in primary care settings for patients with a history of recurrent depression.

We ask a primary policy research question: "Is MBCT superior to m-ADM in terms of: a primary outcome of preventing depressive relapse/recurrence over 24 months; and, secondary outcomes of (a) depression free days, (b) residual depressive symptoms, (c) anti-depressant (ADM) usage, (d) psychiatric co-morbidity, (e) quality of life, and (f) cost effectiveness?"

We ask subsidiary interlinked explanatory questions: "Is an increase in mindfulness skills the key mechanism of change?"

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Not provided at time of registration – submission pending as of 28/04/2009

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

GP practice

### **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**

Recurrent depression

## **Interventions**

Mindfulness-based Cognitive Therapy (MBCT, see <http://www.mbct.co.uk>). MBCT is an 8-week, group based programme (8-15 patients per group) designed to teach people skills that prevent depressive relapse/recurrence. It is a fully manualised psychosocial intervention with the treatment rationale for each session outlined in full. MBCT is based on theoretical and empirical work demonstrating that depressive relapse is associated with the reinstatement of automatic modes of thinking, feeling and behaving that are counter-productive in contributing to depressive relapse and recurrence. Participants learn to recognize these "automatic pilot" modes, decouple from them and use healthier coping methods. MBCT is an accessible and acceptable treatment as evidenced by low attrition in trials (<10%) and shows very promising evidence of efficacy.

The control group will continue to take maintenance anti-depressant medication for the duration of the trial.

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome measure**

To determine whether MBCT is superior to maintenance antidepressant medication (m-ADM) in preventing depression relapse/recurrence over 24 months for patients with a history of recurrent depression.

## **Secondary outcome measures**

A unique aspect of our trial is the inclusion of a range of secondary outcome measures including those highly valued by patients themselves. We will be comparing the following:

1. Number of depression free days
2. Residual depressive symptoms
3. Anti-depressant usage
4. Psychiatric co-morbidity
5. Quality of life, assessed by Euroqol EQ-5D
6. Cost effectiveness

A further secondary objective is to determine whether an increase in mindfulness skills is the key mechanism of change.

All outcome measures will be taken at 3, 6, 12, 18 and 24 months post baseline.

## **Overall study start date**

02/04/2010

## **Completion date**

01/08/2013

## Eligibility

### Key inclusion criteria

1. A diagnosis of recurrent major depressive disorder in full or partial remission according to the Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV), with 3 or more previous major depressive episodes
2. Both males and females, aged 18 or older
3. Patients on a therapeutic dose of ADM in line with the British National Formulary (BNF) and the National Institute for Health and Clinical Excellence (NICE) guidance

### Participant type(s)

Patient

### Age group

Adult

### Lower age limit

18 Years

### Sex

Both

### Target number of participants

420

### Key exclusion criteria

1. Co-morbid diagnoses of current substance dependence
2. Organic brain damage
3. Current/past psychosis, including bipolar disorder
4. Persistent anti-social behaviour
5. Persistent self-injury requiring clinical management/therapy
6. Formal concurrent psychotherapy

### Date of first enrolment

02/04/2010

### Date of final enrolment

01/08/2013

## Locations

### Countries of recruitment

England

United Kingdom

**Study participating centre**  
**University of Exeter**  
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## **Sponsor information**

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University of Exeter (UK)

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University/education

**Website**  
<http://www.exeter.ac.uk/>

**ROR**  
<https://ror.org/03yghzc09>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
Health Technology Assessment Programme

**Alternative Name(s)**  
NIHR Health Technology Assessment Programme, HTA

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

**Location**  
United Kingdom

## 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?
<a href="#">Protocol article</a>	protocol	20/10/2010		Yes	No
<a href="#">Protocol article</a>	protocol update	10/06/2014		Yes	No
<a href="#">Results article</a>	results	04/07/2015		Yes	No
<a href="#">Results article</a>	results	01/09/2015		Yes	No
<a href="#">Results article</a>	qualitative study results	18/02/2020	17/02/2021	Yes	No
<a href="#">Results article</a>	Secondary analysis	01/09/2024	21/10/2024	Yes	No
<a href="#">Results article</a>		08/11/2024	20/11/2024	Yes	No