

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

Submission date 28/04/2009	Recruitment status No longer recruiting	☒ Prospectively registered
		☒ Protocol
Registration date 07/05/2009	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 20/11/2024	Condition category Mental and Behavioural Disorders	☐ 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

Clinical Trials Information System (CTIS)

2009-012428-10

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Prevention

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, decentre 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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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**

United Kingdom

England

Study participating centre

University of Exeter

Exeter

United Kingdom

EX4 4QG

Sponsor information**Organisation**

University of Exeter (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, Health Technology Assessment (HTA), HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/07/2015		Yes	No
Results article	results	01/09/2015		Yes	No
Results article	qualitative study results	18/02/2020	17/02/2021	Yes	No
Results article	Secondary analysis	01/09/2024	21/10/2024	Yes	No
Results article		08/11/2024	20/11/2024	Yes	No
Protocol article	protocol	20/10/2010		Yes	No
Protocol article	protocol update	10/06/2014		Yes	No