ISRCTN26666654 https://doi.org/10.1186/ISRCTN26666654

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

Submission date 28/04/2009	**Recruitment status** No longer recruiting
Registration date 07/05/2009	**Overall study status** Completed
Last Edited 20/11/2024	**Condition category** Mental and Behavioural Disorders

[X] Prospectively registered
[X] 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
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, 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 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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Sponsor type
University/education

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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?
Protocol article	protocol	20/10/2010		Yes	No
Protocol article	protocol update	10/06/2014		Yes	No
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