Trial platform: preventing depression relapse in the National Health Service practice using Mindfulness-Based Cognitive Therapy

Recruitment status No longer recruiting	Prospectively registered	
	☐ Protocol	
Overall study status	Statistical analysis plan	
Completed	[X] Results	
Condition category Mental and Behavioural Disorders	Individual participant data	
	No longer recruiting Overall study status Completed	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number G0401161

Study information

Scientific Title

Acronym

MBCT

Study objectives

Aims:

- 1. To carry out preparatory work necessary to design and conduct an adequately powered, well-controlled, multi-centre randomised controlled effectiveness study of the generalisability of MBCT to real-world National Health Service (NHS) practice settings comparing it to the current treatment of choice (anti-depressant medication)
- 2. To examine key mechanisms that enhance recovery and prevent relapse via a pilot processoutcome study.

Objectives:

- 1. To integrate MBCT into selected primary care service contexts
- 2. To fully cost MBCT
- 3. To establish patient throughput numbers
- 4. To develop training and supervision packages for MBCT therapists
- 5. To pilot measures of mechanisms of change, health status and cost-effectiveness
- 6. To estimate MBCT effect sizes in real-world conditions
- 7. To resolve methodology/design issues for the phase IV study, including necessary sample size (based on points one, two & five above), feasibility/method of randomising patients with remitted depression to pharmacological and MBCT treatment arms and optimal follow-up periods

Ethics approval required

Old ethics approval format

Ethics approval(s)

North and East Devon research ethics committee project (reference number: 05/Q2102/77) approval given 8th August 2005.

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Depression

Interventions

Continuation anti-depressants or Mindfulness-based Cognitive Therapy.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

In line with previous MBCT randomised controlled trials (RCTs), the primary outcome measure will be a recurrence of depression meeting DSM-IV criteria.

Key secondary outcome(s))

Secondary outcome measures will be residual depressive symptoms (measured by the interviewer-rated Hamilton Depression Scale and self-report Beck Depression Inventory). In line with effectiveness trials examining an interventions generalisability, a novel feature of this study will be extending outcome assessment to health status (using the Medical Outcomes Study [MOS SF-12] instrument), quality of life (using the World Health Organisation Quality of Life [WHOQOL-BREF] instrument), and health costs (using Client Service Receipt Inventory adapted for depression relapse studies).

Completion date

30/09/2007

Eligibility

Key inclusion criteria

- 1. Three or more previous episodes of depression meeting the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria (including the current episode)
- 2. Aged 18 or older
- 3. Currently in either partial or full remission from last episode of depression

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Co-morbid psychiatric diagnoses that would:

- 1. Interfere with engaging with MBCT (current substance dependence)
- 2. Be exacerbated by MBCT (psychosis, very disabling obsessive compulsive disorder) and formal concurrent psychotherapy

Date of first enrolment

01/09/2005

Date of final enrolment

30/09/2007

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

Research council

Funder Name

Medical Research Council (MRC) (UK) (ref: G0401161)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

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

Not provided at time of registration

Study outputs

Output type	Details	Date created Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2008	Yes	No
Results article	results	01/07/2009	Yes	No
Results article	results	01/06/2010	Yes	No
Results article	results of sub-study on effect on parenting	01/01/2012	Yes	No