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

Submission date	Recruitment status	[_] Prospectively registered
27/06/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/08/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/07/2012	Mental and Behavioural Disorders	

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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 process-outcome 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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

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

Secondary outcome measures
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).

Overall study start date
01/09/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40 in MBCT and 40 in continuation anti-depressants

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
England

United Kingdom

Study participating centre
University of Exeter
Exeter
United Kingdom
EX4 4QG

Sponsor information

Organisation
University of Exeter (UK)

Sponsor details
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Sponsor type
University/education

Website
http://www.exeter.ac.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

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?
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