

# Mindfulness Based Cognitive Therapy for parents with recurrent depression: compared to care as usual

<b>Submission date</b> 23/05/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/11/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 09/06/2017	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

In this study we aim to find out whether a mindfulness-based cognitive therapy course for parents (MBCT-P) is helpful in reducing levels of depression and parental stress. We are also interested in whether this therapy has any effect on parenting and children's behaviour. This study will give us an initial understanding of whether this therapy could be helpful and therefore allow us to see whether a larger study can take place.

### Who can participate?

Men and women aged 18 or over who have experienced three or more depressive episodes in the past, are in full or partial remission from depression, and have a child between the ages of 2 – 6.

### What does the study involve?

Participants will be randomly allocated into one of two groups. The first group will receive the MBCT-P therapy course and the second group will continue with any care which they currently receive (in some cases they may not be receiving any care). If you are interested in taking part you will initially talk to a researcher over the phone and then meet them in order to answer some questions which will help us to see if you are eligible to take part. If you are eligible you will then complete a short interview and some questionnaires both at the beginning of the trial and 4 months and 9 months after you are allocated to a group. You will also be asked if you are happy to complete questionnaires weekly during the time that the therapy group is taking place. This helps us to compare the two groups over this time period.

### What are the possible benefits and risks of participating?

Everyone who takes part will have a chance to take part in an MBCT group for parents (dependent on whether they are allocated to the therapy group). Although no one who takes part will be currently experiencing an episode of depression they may be experiencing some symptoms of depression. If anyone is thought to be at risk to themselves or anyone else then their GP or another appropriate clinician will be informed.

Where is the study run from?  
Peninsula College of Medicine and Dentistry (UK).

When is the study starting and how long is it expected to run for?  
From April 2011 to January 2012.

Who is funding the study?  
Medical Research Council (MRC) (UK).

Who is the main contact?  
Joanna Mann  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
1.2

## Study information

**Scientific Title**  
Mindfulness Based Cognitive Therapy for parents with recurrent depression: an exploratory randomised controlled trial

**Acronym**  
MBCT-P

**Study objectives**  
The trial aims to assess whether it is feasible to progress onto a definitive trial to explore the effectiveness of MBCT-P and whether MBCT-P is acceptable to parents with recurrent depression.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

South West 3 Research Ethics Committee, 27/01/2011, ref: 10/H0106/81

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Recurrent depression

**Interventions**

The MBCT-P trial has two arms. Participants allocated to the treatment arm take part in a baseline assessment and then receive eight weeks of therapy, which consists of a 2 hour 15 minute (two of the sessions are 2 hours and 30 minutes) therapy session each week. They will take part in follow-ups at four and nine months post randomisation.

Participants randomly allocated to usual care will have a baseline assessment and then continue with any care they currently receive and any which they decide to start during the trial. They will also have assessments at four and nine months post randomisation.

All participants will also complete questionnaires during the eight weeks which the therapy is taking place (regardless of arm).

**Intervention Type**

Behavioural

**Primary outcome(s)**

Depressive symptoms as measured by the The Beck Depression Inventory (BDI-II)

**Key secondary outcome(s)**

1. Parenting stress as measured by the Parenting Stress Index, Short Form (PSI-SF)
  2. Childrens' behaviour as measured by the Eyberg Child Behavior Inventory (ECBI) and Strengths and Difficulties Questionnaire (SDQ)
  3. Quality of life
  4. Explore whether changes in levels of mindfulness skills could be a possible mechanism of change:
    - 4.1. Quantitative measurement of potential mediating variables
    - 4.2. A parent observational study
    - 4.3. An embedded qualitative study to elicit participants' experiences of treatment
- All outcome measures will be taken at baseline, 4 and 9 months post randomisation

**Completion date**

30/10/2012

# Eligibility

## Key inclusion criteria

1. A diagnosis of full or partial remission from depression according to the Diagnostic and Statistical Manual for Mental Disorders Fourth Edition (DSM-IV-TR)
2. Age 18 years +
3. A parent (mother or father) of a child aged between 2 - 6 years
4. Have experienced 3 or more previous major depressive episodes according to the Diagnostic and Statistical Manual for Mental Disorders fourth addition DSM-IV-TR

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Sex

All

## Key exclusion criteria

1. Current substance dependence
2. Organic brain damage
3. Current or past psychosis including bipolar disorder
4. Anti-social behaviour or persitant self-harm
5. Already receieving psychological therapy
6. Significant longstanding interpersonal difficulties that require specialist and long-term psychological treatment
7. A parent of a child who is known to be vulnerable or at risk

## Date of first enrolment

20/02/2011

## Date of final enrolment

30/10/2012

# Locations

## Countries of recruitment

United Kingdom

England

**Study participating centre**  
Peninsula College of Medicine and Dentistry  
Exeter  
United Kingdom  
EX2 4SG

## 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)

**Alternative Name(s)**  
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory 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?
<a href="#">Results article</a>	results	01/02/2016		Yes	No