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

Submission date
23/05/2011

Recruitment status
No longer recruiting

Registration date
30/11/2011

Overall study status
Completed

Last Edited
09/06/2017

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
The MBCT-P trial has two arms. Participants allocated to the treatment arm take part in a baseline assessment and then recieve 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 randomlly 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 measure

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

Secondary outcome measures
1. Parenting stess 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

Overall study start date
20/02/2011

Completion date
30/10/2012

Eligibility

Key inclusion criteria
1. A diagnosis of full or partial resmission 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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
90

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
England

United Kingdom

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

Sponsor information

Organisation
University of Exeter (UK)

Sponsor details
c/o Michael Wykes
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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)

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	01/02/2016		Yes	No