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Oxford Postnatal Treatment Study: treatment for mothers with postnatal depression to improve child outcome

Submission date
24/09/2010

Recruitment status
No longer recruiting

Registration date
28/09/2010

Overall study status
Completed

Last Edited
14/02/2018

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Maternal postnatal depression (PND) is a major public health issue: it affects around 13% of mothers, and compared to children of non-depressed mothers, the children of mothers with PND are more likely to have learning, behavioural and attachment problems. Treating maternal depression alone does not improve child outcome. An intervention focusing on mother-child interactions is needed to promote these children's development. We aim to examine whether, in the context of PND, a treatment to enhance mother-child interactions leads to improved child outcome. Furthermore, since treatment can be targeted at critical aspects of functioning, a treatment study provides an opportunity to examine potential causal factors in determining child outcome. Thus, this study will focus treatment on improving three key parenting capacities that are known to be compromised in PND, and examine whether this improves children's outcomes.

Who can participate?
Mothers of babies between 5-9 months with PND (a full diagnostic interview will be conducted) who live within a 35 mile radius of Headington, Oxford

What does the study involve?
Mothers with PND receive home-based treatment from about six months postpartum. They are then randomly allocated to one of two treatments: either a treatment using video-feedback (index) to improve mother-child interactions or relaxation training (control). Both groups also receive cognitive behaviour therapy (CBT) for depression. In total each participant receives 11 home-based therapy sessions lasting a few months altogether (between baby age 6-12 months), followed by two booster therapy sessions when their baby is around 16 months old. The two groups are compared post treatment (child age one year) and at follow-up (child age two years) where there are further assessment visits (at home, and one in our offices in Headington, Oxford).

What are the possible benefits and risks of participating?
CBT, which all participants will receive, is the treatment recommended by the NHS for people

with depression. CBT can help an individual to make changes to the areas of their life that they are not happy with at the moment and may help people to feel better. Relaxation therapy has been shown to be an effective method of helping people to reduce tension, and is a skill that can be used at any time. The support for mother-baby communication using video-feedback treatment has been used in several research studies with mothers and babies, and in general they have enjoyed it and found it to be helpful. Participants need to put aside about an hour and a half for each therapy and assessment session. They may find some of the things we discuss with you upsetting.

Where is the study run from?
University of Oxford (UK).

When is the study starting and how long is it expected to run for?
December 2010 to August 2015

Who is funding the study?
Wellcome Trust (UK)

Who is the main contact?
Mrs Valerie West or Professor Alan Stein
info@opt-study.org

Contact information

Type(s)
Scientific

Contact name
Prof Alan Stein

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

090139

Study information

Scientific Title
A randomised controlled treatment trial for mothers with postnatal depression to improve children's cognitive, behavioural and attachment outcomes, as well as to treat the mothers' depression

Study objectives
In the context of postnatal depression, compared to a control treatment (progressive muscle relaxation [PMR]) the index treatment (targeting mother-infant interaction) will lead to better cognitive development, fewer behaviour problems, and a higher rate of secure attachment in the children (where mothers in both groups receive cognitive behavioural therapy [CBT] for their depression).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Berkshire Research Ethics Committee, 05/08/2010, ref: 10/H0505/55

Study design
Single-centre randomised controlled assessor-blinded interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request patient information material

Health condition(s) or problem(s) studied
Postnatal depression

Interventions
There are three therapies which constitute the study interventions:
1. The index group will receive a treatment aimed specifically to improve mother-infant interaction
2. The control treatment will receive progressive muscle relaxation (PMR)
3. All participants will also receive cognitive behaviour therapy (CBT) for their depression

All therapies will be delivered to each participant by the same therapist in the participant's home. Treatment will begin when the infant is 6 - 8 months of age. Initially there will be five weekly sessions, followed by five fortnightly sessions. There will be two booster sessions when the child is 16 and 20 months of age respectively.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measures as of 28/11/2017:
When the infant is 24 months of age:
1. Child cognitive and language development were measured using the Bayley Scales of Infant Development-Third Edition (BSID-III).
2. Behaviour problems will be assessed by the Child Behaviour Checklist (CBCL). The principal outcome will be the externalising scale of the CBCL (completed by the mother).
3. Attachment security will be measured by the Attachment QSort (AQS), comprising 90 items designed to measure the security of a child's attachment behaviour during naturalistic observations in the family home over a period of approximately 1.5 hours.

Previous primary outcome measures:
When the infant is 24 months of age:
1. Child cognitive development will be measured using the Bayley Scales of Infant Development Third Edition (BSIDIII). We will use the Mental Development Index as the principal outcome.
2. Behaviour problems will be assessed by the Child Behaviour Checklist (CBCL). The principal outcome will be the externalising scale of the CBCL (completed by the mother and another caregiver).
3. Attachment security will be measured by the Attachment QSort (AQS), comprising 90 items designed to measure the security of a child's attachment behaviour during naturalistic observations in the family home over a period of approximately 1.5 hours.

Secondary outcome measures
Current secondary outcome measures as of 28/11/2017:
When the infant is 24 months of age:
1. Maternal depression will be measured using the Edinburgh Postnatal Depression Scale (EPDS) and Structured Interview for DSM IV Diagnosis (SCID). Depression at 24 months will be used as a secondary outcome.
2. Emotion regulation, measured using the barrier paradigm from the LABTAB battery.
3. Sustained Infant Attention will be measured using the ECBQ (Early Childhood Behaviour Questionnaire) for child attention.
4. Children’s ability to discriminate facial expressions of emotion, measured using the emotion discrimination task. Positive (happy), negative (sad) and neutral (calm) adult faces were presented for 100 ms each on a screen linked to an eye-tracker.

Previous secondary outcome measures:
When the infant is 24 months of age:
1. Maternal depression will be measured using the Edinburgh Postnatal Depression Scale (EPDS) and Structured Interview for DSM IV Diagnosis (SCID). Depression at 24 months will be used as a secondary outcome.

2. Emotion regulation - two standardised tests of infant temperament will be used to elicit emotion regulation in the infants, taken from the LABTAB battery. The mean of the emotional regulation scores across both tasks will be used.
3. Sustained Infant Attention will be measured using both manual responses by the child and eyetracking using a version of the continuous performance test designed for use with 24 month olds.

Overall study start date
01/12/2010

Completion date
31/08/2015

Eligibility

Key inclusion criteria
1. Diagnosed with postnatal depression fulfilling criteria for major depressive disorder for at least 3 months duration
2. Willing and able to give informed consent for participation in the study
3. Aged 18 years or above
4. 5 - 8 months postpartum at screening
5. Infant born at 35 weeks gestation or more
6. Infant birthweight of 2000 g or more

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
144 (72 in each arm)

Key exclusion criteria
1. Other severe psychiatric diagnosis
2. Life threatening or other serious physical illness
3. Serious illness or medical complication in the infant
4. Unable to converse in English
5. Mother not cohabiting with the infant

Date of first enrolment
01/03/2011

Date of final enrolment

30/10/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford University
Oxford
United Kingdom
OX3 7JX

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
CTRG, Manor House
John Radcliffe Hospital
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England
United Kingdom
OX3 9DU

Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust (grant ref: 090139)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publications in high impact peer reviewed journals.

Intention to publish date

Individual participant data (IPD) sharing plan
Individual participant data that underlie the results reported in the published articles will be made available, after de-identification. The study protocol and statistical analysis plan will also be made available. Data will be available to researchers who provide a methodologically sound proposal to either achieve the aims in an approved research proposal or for individual participant data meta-analysis, from 9 months after publication. Proposals should be directed to alan.stein@psych.ox.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2018		Yes	No