

Antidepressant drug therapy vs a community-based psychosocial intervention for the treatment of moderate postnatal depression: a pragmatic randomised controlled trial

Submission date 16/09/2003	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 16/09/2003	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 08/08/2011	Condition category Mental and Behavioural Disorders	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HTA 02/07/04

Study information

Scientific Title

Acronym

RESPOND

Study objectives

The study proposes to compare the effectiveness and cost-effectiveness of antidepressant drug therapy versus a community-based psychosocial intervention (Health Visitor delivered non-directive counselling) in the treatment of moderate postnatal depression.

Protocol can be found at: <http://www.hta.ac.uk/protocols/200200070004.pdf>

More details can be found at: <http://www.hta.ac.uk/1373>

Please note that, as of 11 January 2008, the anticipated start and end dates of this trial have been updated from 1 March 2004 and 30 September 2007 to 1 June 2004 and 30 April 2008, respectively.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration.

Primary study design

Intentional

Study design

Two arm multi-centre pragmatic randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Postnatal depression

Interventions

A two arm multi-centre pragmatic randomised controlled trial, with randomisation at the level of the individual woman. Women who reach the threshold for inclusion (EPDS>12, CIS-R>11) at 8 weeks will be randomised to either antidepressants or a 4 week waiting list for counselling. Women who do not respond to the allocated therapy in their group will be offered the opportunity to either switch or combined therapies after the primary outcome has been measured (4 weeks for antidepressants, 18 weeks for counselling) Thus the research design allows women to receive both antidepressants and psychological therapy is required.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Antidepressants

Primary outcome(s)

The primary outcome measure is the EPDS at 4 weeks, 18 weeks and 44 weeks. In addition, the trial will use the SF-36 as a generic measure of functional quality of life, the EQ5D for economic analysis, the MAMA for parenting skills and attitudes towards the baby, the GRIMS for the quality of the marital relationship. The trial will ask partners to complete the GHQ12 the PAPA and the GRIMS. At 12 months we will assess the family milieu using the HOME and the child's development using the Bayley scales.

Key secondary outcome(s)

Not provided at time of registration.

Completion date

30/04/2008

Eligibility**Key inclusion criteria**

Women with post natal depression up to 3 months post natal

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Not provided at time of registration.

Date of first enrolment

01/06/2004

Date of final enrolment

30/04/2008

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre
Academic Unit of primary care
Bristol
United Kingdom
BS8 2AA

Sponsor information

Organisation
Department of Health (UK)

ROR
<https://ror.org/03sbpja79>

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

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	01/09/2010		Yes	No
Results article	results	03/08/2011		Yes	No