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# 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

**Registration date**
16/09/2003

**Overall study status**
Completed

**Last Edited**
08/08/2011

**Condition category**
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 trail 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.

## Study design
Two arm multi-centre pragmatic randomised controlled trial

## Primary study design
Interventional

## 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 |