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Psychological interventions for postnatal depression - randomised controlled trial and economic evaluation

Submission date	Recruitment status	[ ] Prospectively registered
25/04/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/04/2003	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/05/2020	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.sheffield.ac.uk/scharr/sections/heds/staff/ponder.html

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 99/33/51

Study information

Scientific Title
Psychological interventions for postnatal depression - randomised controlled trial and economic evaluation

Acronym
PONDER

Study objectives
The central aim of the study is to assess the costs, effectiveness and broad impact of screening for postnatal depression alongside two counselling interventions, non-directive counselling and cognitive behavioural counselling, delivered by health visitors in their usual clinical setting. Screened women at risk of depression will be interviewed to assess symptom severity. The study will assess effectiveness according to severity, history and duration of depression. The design will reflect the practicalities of primary care service delivery and will ensure that a wide range of effects is identified. In addition, the trial will examine an important practical question, with no loss of statistical power, on the efficiency and value of face-to-face screening by health visitors, compared with postnatal screening.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Screening

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

Mental and behavioural disorders: Depression, anxiety, neuroses; Pregnancy and childbirth: Childbirth

Interventions
Non-directive counselling (NDC) v Cognitive Behavioural-type Counselling (CBC) delivered by Health Visitors in their usual clinical setting v standard care

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The efficiency and value of face-to-face screening by health visitors, compared with postnatal screening. Women's postal questionnaires, casenotes and activity data will be used to monitor changes in symptoms, health outcomes, hospital admissions, NHS service use, family well-being and infant progress to eighteen months

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/04/2003

Completion date
31/03/2006

Eligibility

Key inclusion criteria
Women with live babies who will remain with their GP for 4 months

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
4000 women from 93 General Practices

Key exclusion criteria
Unable to give informed consent

Date of first enrolment
01/04/2003

Date of final enrolment
31/03/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Research Leader
Huddersfield
United Kingdom
HD1 3DH

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Quarry House
Quarry Hill
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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

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

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	15/01/2009		Yes	No
Other publications	cost-benefit analysis	01/06/2009		Yes	No
Results article	cost-effectiveness results	01/06/2019	15/05/2020	Yes	No