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The costs and benefits of post-natal midwifery support - a randomised controlled trial

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
27/08/2009	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 94/22/24

Study information

Scientific Title

Study objectives
This study aimed to measure the effect and the total cost per woman of providing postnatal support at home, based on a Dutch model. The research hypothesis was furnished by some existing evidence that postnatal support could reduce the risk of postnatal depression and encourage breastfeeding.

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Pregnancy and childbirth: Childbirth

Interventions
The randomised controlled trial aimed to measure differences in health status in a group of women who were offered postnatal support from a community midwifery support worker (SW) compared with a control group of women who were not offered this support. Women were followed-up by postal questionnaire at 6 weeks and 6 months postnatally.
The intervention consisted of the SW offering practical and emotional support and to help women rest and recover after childbirth. The SW offered ten visits in the first 28 days postnatally, for up to 3 hours per day. The SW's activities included housework, talking with the mother, and care for the baby or other siblings. The service was provided in addition to routine visits by the community midwife.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary outcome was the general health perception domain of the Short Form-36 at 6 weeks.

Secondary outcome measures
Secondary outcomes were mean Edinburgh Postnatal Depression Scale (EPDS), Duke Functional Social Support (DUFSS) scores and breastfeeding rates.

Overall study start date
01/06/1996

Completion date
31/08/1998

Eligibility

Key inclusion criteria
All women who delivered a baby at the recruiting hospital were eligible to take part in the trial if they lived within the study area, were aged 17 years or over, and could understand English.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Not provided at time of registration.

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
01/06/1996

Date of final enrolment
31/08/1998

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of General Practice and Primary Care
Sheffield
United Kingdom
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Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Quarry House
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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?
Other publications	HTA monograph	01/02/2000		Yes	No
Results article	results	09/09/2000		Yes	No