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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
25/04/2003		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
25/04/2003		[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

Contact name

Ms Jane Morrell

Contact details

Institute of General Practice and Primary Care University of Sheffield
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU
+44 (0)114 249 2500
j.morrell@sheffield.ac.uk

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

Study participating centre Institute of General Practice and Primary Care Sheffield United Kingdom S5 7AU

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Quarry House Quarry Hill Leeds United Kingdom LS2 7UE +44 (0)1132 545 843 Sheila.Greener@doh.gsi.gov.uk

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