ISRCTN79350792 https://doi.org/10.1186/ISRCTN79350792

Redesigning postnatal care: a randomised controlled trial of protocol-based, midwifery-led care

Submission date
25/04/2003

Recruitment status
No longer recruiting

Registration date
25/04/2003

Overall study status
Completed

Last Edited
01/04/2022

Condition category
Pregnancy and Childbirth

[_] 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

Contact name
Prof Christine MacArthur

Contact details
Dept of Public Health & Epidemiology
University of Birmingham
Edgbaston
Birmingham
United Kingdom
B15 2TT
+44 0121 414 6770
C.MacArthur@bham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 94/22/26

Study information

Scientific Title
Redesigning postnatal care: a randomised controlled trial of protocol-based, midwifery-led care

Study objectives
Recent government reports have highlighted the need for change in the provision of maternity care. The objective of this study is to develop and implement two new models of postnatal care. The cost-effectiveness of the models will be compared with current practice in a three arm randomised controlled trial. The new models will comprise midwifery-led protocol-based care, aimed at the identification and management of individual women's physical and psychological health problems. They are designed to make more appropriate use of the skills and time of the professionals involved. The role of the midwife will be extended to undertake the postnatal examination, with GP referral based on need. The content and frequency of postnatal consultations will be substantially modified and there will be a reduction in routine monitoring, observations and examinations. In one intervention arm the new model of care will extend until three months postpartum. The findings will have direct implications for delivery of care throughout the National Health Service.

Ethics approval required
Old ethics approval format

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

Study design
Cluster 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
Childbirth

Interventions
1. New model of community care
2. Standard community post natal care

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Outcomes will be assessed by measures of physical and emotional well-being and satisfaction with care.

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/05/1996

Completion date
31/03/2000

Eligibility

Key inclusion criteria
Consenting cluster practices

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
2,064

Total final enrolment
2064

Key exclusion criteria
Women expected to move out of the general practice in the post-natal period.

Date of first enrolment
01/05/1996

Date of final enrolment
31/03/2000

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Dept of Public Health & Epidemiology
Birmingham
United Kingdom
B15 2TT

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
Not provided at time of registration

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		01/01/2003		Yes	No