

Extending Midwife/nurse Roles in the routine Examination of the Newborn: randomised controlled evaluation and cost-effectiveness (EMREN trial)

Submission date 25/04/2003	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 25/04/2003	Overall study status Completed	☐ Protocol
Last Edited 08/11/2022	Condition category Pregnancy and Childbirth	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

HTA 94/40/05

Study information

Scientific Title

Extending Midwife/nurse Roles in the routine Examination of the Newborn: randomised controlled evaluation and cost-effectiveness (EMREN trial)

Acronym

EMREN

Study objectives

The project will evaluate the cost effectiveness of extending midwifery practice in the routine examination of the newborn. The main study is an RCT, with 1000 babies in each arm, of outcome and cost effectiveness of examination by trained junior doctors compared with examination by trained midwives. The value of a further examination at ten days will also be assessed. In depth interviews will be held with paediatricians, midwives, GPs, nurses, patients and Royal Colleges. Effects on the NHS labour market and training needs will be analysed. The research addressed general and specific issues of extending nursing and midwifery roles, concerns regarding junior doctor hours and the timing of examinations of newborn babies, and will inform NHS policy.

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

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Childbirth

Interventions

1. Neonatal examination by trained junior doctors
2. Neonatal examination by trained mid-wives

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Referrals assessed as appropriate and as major or minor by three independent consultants. Problems identified during the first year of life assessed as identifiable at 24 hours. Quality assessment by video against an agreed written proforma. Maternal satisfaction. Opinion of professionals and mothers about aspects of the examination.

Key secondary outcome(s))

Not provided at time of registration.

Completion date

31/08/2001

Eligibility

Key inclusion criteria

Newborn infants

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration.

Date of first enrolment

01/03/1999

Date of final enrolment

31/08/2001

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

The Public & Environmental Health Research Unit (PEHRU)

London

United Kingdom
WC1E 7HT

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

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	HTA monograph	01/04/2004		Yes	No