

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

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<b>Registration date</b> 25/04/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 08/11/2022	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

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

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

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

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.

**Secondary outcome measures**

Not provided at time of registration.

**Overall study start date**

01/03/1999

**Completion date**

31/08/2001

**Eligibility****Key inclusion criteria**

Newborn infants

**Participant type(s)**

Patient

**Age group**

Neonate

**Sex**

Not Specified

**Target number of participants**

2000

**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

England

United Kingdom

## Study participating centre

The Public & Environmental Health Research Unit (PEHRU)

London

United Kingdom

WC1E 7HT

# 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

## 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?
<a href="#">Results article</a>	HTA monograph	01/04/2004		Yes	No