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North-East Cot (NECOT) Trial: Postnatal care and breastfeeding duration

Submission date	Recruitment status	[_] Prospectively registered
02/04/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/06/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/01/2016	Neonatal Diseases	

Plain English summary of protocol

Background and study aims
It is well known that close contact between mums and babies at night makes it easier to establish breastfeeding, and to continue breastfeeding for longer. Close contact allows the baby to suckle more frequently, which helps with initiation of breastfeeding, and also with establishing a good long-term milk supply. While we know that close contact is good for breastfeeding, some people have concerns about mums and babies sharing a bed, especially in the immediate postnatal period when mums may have had pain relief potentially affecting their awareness of the baby. Our previous research demonstrated that using a side-car crib instead of a stand-alone bassinette resulted in mums and babies interacting in the same way as if they were sharing the same bed. They also breastfed for significantly longer – more than twice as many 'side-car' mums than 'standalone crib' mums were still breastfeeding at 16 weeks. We wanted to find out if we would still obtain this result when the side-car cribs were used on a much larger scale.

Who can participate?
Women who intend to breastfeed their baby in the postnatal ward

What does the study involve?
Participants are randomly assigned to receive either the side-car or standalone crib, and are asked to report on their infant's feeding and sleeping until their baby is 6 months old.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Royal Victoria Infirmary (UK)

When is the study starting and how long is it expected to run for?
January 2008 to January 2010

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Prof Helen Ball

Contact information

Type(s)
Scientific

Contact name
Prof Helen Ball

Contact details
Department of Anthropology
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United Kingdom
DH1 3HN

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
3433

Study information

Scientific Title
North-East Cot (NECOT) Trial: Postnatal care and breastfeeding duration

Acronym
NECOT

Study objectives
Trial aims to address whether infant proximity to mother on postnatal ward affects long-term breastfeeding outcomes (to be assessed by use of two cot types).

Ethics approval required
Old ethics approval format

Ethics approval(s)
County Durham and Tees Valley 2 Research Ethics Committee, 22/08/2007, ref: 07/H0908/57

Study design

Randomised non-blinded trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Patient information can be found at: http://www.dur.ac.uk/sleep.lab/necot/

Health condition(s) or problem(s) studied
Postnatal care

Interventions
Side-car crib vs stand alone bassinette

Duration of intervention: For the duration of the postnatal ward stay (typically 24 hours)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Time to cessation of exclusive breast-feeding (baby receiving any food item other than breastmilk in preceding week)
2. Time to cessation of any breast feeding (baby receiving no breastmilk for at least 2 consecutive weeks)

Secondary outcome measures
1. Percentage of weeks in which any bed-sharing is reported (presence/absence of bed-sharing in preceding week). Participants will provide weekly data regarding this variable for 6 months. The outcome will be assessed at end of 6 month follow-up period.
2. Percentage of weeks in which infant illness is reported (presence/absence of contact with health professional due to concern for infant health in preceding week). Participants will provide weekly data regarding this variable for 6 months. The outcome will be assessed at end of 6 month follow-up period.
3. Duration of post-natal ward stay
4. Prenatal propensity to breastfeed (likert scale), data obtained at enrolment
5. Prenatal attitude to breastfeeding (likert scale), data obtained at enrolment

Overall study start date
07/01/2008

Completion date
07/01/2010

Eligibility

Key inclusion criteria
1. Women with normal singleton pregnancies
2. Prenatal intention to breastfeed
3. Informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
800

Key exclusion criteria
1. Multiple pregnancies
2. Foetal anomalies
3. Ill mother or baby following delivery
4. No prenatal intention to breastfeed

Date of first enrolment
07/01/2008

Date of final enrolment
07/01/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Durham University
Durham
United Kingdom
DH1 3HN

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details
c/o Dr Lesley Hall
Research Governance Manager
Newcastle upon Tyne Hospitals NHS Foundation Trust
R&D Department
4th Floor
Leazes Wing
Royal Victoria Infirmary
Queen Victoria Road
Newcastle-upon-Tyne
England
United Kingdom
NE1 4LP

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR), Research for Patient Benefit (RfPB) programme (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

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?
Results article	results	01/07/2011		Yes	No