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A randomised controlled trial to compare alternative strategies for preventing infant crying and sleeping problems in the first 3 months of life

Submission date
23/01/2004

Registration date
23/01/2004

Last Edited
19/11/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Neonatal Diseases

[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MCH 09-06

Study information

Scientific Title

Study objectives
The primary aim was to measure the effects of a behavioural intervention on infant crying and sleeping behaviour in the first three months compared with a potentially low cost educational intervention and existing service provision within the NHS. An economic evaluation was designed to estimate the annual cost to the NHS of infant crying and sleeping problems in the first 12 weeks of life and to assess the cost effectiveness of interventions aimed to prevent infant crying and sleeping problems relative to the usual services.

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)
Other

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Infant crying and sleeping problems

Interventions
A randomised controlled trial in which mother and baby pairs were allocated to one of 3 policies.
1. The behavioural intervention encouraged mothers to accentuate day/night differences so that babies learned to regulate sleep and waking behaviour according to environmental cues. This involved introducing a late evening focal feed, trying not to rock, hold or feed babies to sleep, to settle them in a darkened environment and to minimise interaction during the night.
2. The educational intervention comprised an information booklet which incorporated current best practice related to managing/preventing infant crying and promoting good sleeping

patterns. This was prepared in collaboration with Health Visitors. Mothers were also provided with a dedicated telephone help-line organised by a voluntary support group CRYSIS.
3. The control group mothers and babies received the standard community services offered by Health Visitors and GPs as did all the trial participants.
Randomisation was delayed until the mother was at home in order to allow time for recovery following childbirth and to minimise the risk of mergence between the policies. Throughout the first 12 weeks, contact with Health Visitors and/or GPs regarding infants' crying/sleeping problems were recorded; in addition, the babies' weight gain, health and use of medications were monitored. At 9 months mothers' reported whether or not their babies had a regular bedtime routine and whether they had sought professional advice because of their babies' crying or sleeping problems.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Number of 'interruption-free nights' per week
2. Measures of babies' crying.
An 'interruption-free night' was defined as a night in which parents reported their baby to remain asleep for 5 hours or more between 10pm and 6am.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/1996

Completion date
01/09/1997

Eligibility

Key inclusion criteria
Mothers were eligible for inclusion if:
1. they gave birth to their babies at the Royal Berkshire Hospital, Reading
2. they lived in West Berkshire or South Oxfordshire
3. were English speaking and literate
4. owned a telephone
5. their babies were >37 weeks gestation and had not been admitted to Special Care Baby Unit or shown evidence of congenital abnormality

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
610 (behavioural programme [n = 205], educational intervention [n = 202], or control [n = 203]) (Added 19/11/09)

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/09/1996

Date of final enrolment
01/09/1997

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre for Evidence-based Practice
Reading
United Kingdom
RG1 5AN

Sponsor information

Organisation
Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Not defined

Funder Name
NHS Mother and Child Health National Research and Development Programme (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?
Results article	results on cost analysis	01/01/2001		Yes	No
Results article	results	01/06/2001		Yes	No