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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	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 19/11/2009	**Condition category** Neonatal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Other

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(s)
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.

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

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
United Kingdom

England

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)

Funder(s)

Funder type
Not defined

Funder Name
NHS Mother and Child Health National Research and Development Programme (UK)

Results and Publications

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