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Night waking reduction in Canadian infants: the Rocky Sleep Study

Submission date	Recruitment status
11/07/2009	No longer recruiting
Registration date	**Overall study status**
14/07/2009	Completed
Last Edited	**Condition category**
16/11/2015	Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English Summary
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Wendy Hall

Contact details
T. 201 2211 Wesbrook Mall
School of Nursing
University of British Columbia
Vancouver
Canada
V6T 2B5
+1 (0)604 822 7447
Wendy.hall@nursing.ubc.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00877162

Secondary identifying numbers
MCT-94836

Study information

Scientific Title
Night waking reduction in Canadian infants: a randomised controlled trial of a parent-based cognitive and behavioural intervention in community health units

Study hypothesis
In a population of parents who have infants with behavioural sleep problems, are parents randomised to a cognitive-behavioural sleep intervention compared to parents randomised to a group cognitive-behavioural safety intervention more or less likely to:
1. Identify their child as having a severe sleep problem, or
2. To have their child wake fewer than an average of two times per night over five nights by actigraphy?

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of British Columbia Behavioural Ethics Review Board, 23/06/2009, ref: H09-00757

Study design
Randomised single-centre controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Condition
Behavioural sleep problems

Interventions
Current interventions as of 16/05/2013 (this change was due to an error in the original application):
Following randomisation, both groups receive a two hour teaching session delivered to both parents in two parent families or one parent in single-parent families and telephone calls. Five groups of parents at each health unit (5 units) attend two hour teaching sessions (either sleep-based or safety-based). Two telephone calls per week for two weeks support the parent leading

the intervention by focusing on reinforcing the knowledge and skills obtained from the two-hour teaching session. After the six-week data collection point, the sleep group receives a pamphlet on managing infant safety and the safety group receives a pamphlet about managing infant sleep problems.

Experimental Group:
The teaching session for the intervention group and the follow-up phone calls, which were developed by Hall for the pilot study, will be delivered by PHNs who have been trained by the research team. This intervention aims to change parents' cognitions about areas, such as normal infant sleep, effects of inadequate sleep for infants and parents, setting limits around infant sleep, feeding infants to sleep, and infant sleep safety. It introduces behaviours parents can use to promote sleep self-initiation in infants. Parents receive instructions for completing charts so they can track their use of routines and controlled comforting and changes in infant sleep and settling. A videotaped recording of an infant in light and deep sleep, and a videotaped recording of an interview with parents about living with their infant's sleep problem will be shown. The session ends with a question and answer period. Parent handouts include: a paper copy of the scripted Power Point presentation, five copies of the weekly sleep-wake-feed charts and 10 copies of the controlled crying/comforting charts. To reinforce information and provide support for the parent leading the intervention, PHNs will make two telephone calls per week for two weeks. The calls will include questions to determine how best to provide support:
1. How are parents managing?
2. Which strategies are they using to deal with the sleep problem?
3. What are the effects of those strategies on the infant and parents?
4. What, if any, difficulties are they experiencing?
PHNs will also provide a check list of points and standard responses to requests by family members for assistance beyond the sleep intervention.

Control Group:
The safety teaching session for the control group and the follow-up phone calls to support the parent leading the intervention are undertaken by research team members. Safety is the topic, because shaken baby syndrome is a possibility, if parents become angry about constant sleep disruptions. The session includes content about shaken baby syndrome, choking prevention, fall prevention, sleep positioning, hazards of infant walkers, motor vehicle safety, pacifier safety, toy safety, and suffocation, strangulation, drowning, animal bite, poisoning, and burn prevention. Co-sleeping as a risk to infant safety is not discussed. The safety teaching session is scripted using a Power Point CD. Parents will receive a paper handout. Two telephone calls per week for two weeks using the same questions as the intervention group support the lead parent's efforts to use safety strategies. The calls will include the following questions:
1. How are the parents managing?
2. Which strategies are they using to deal with the safety problem?
3. What are the effects of those strategies on the infants and parents?
Registered nurses will also provide a checklist of points and standard responses to requests by family members for assistance beyond the safety intervention.

The total duration of treatment is three weeks (one two-hour teaching session, and two weeks of twice weekly follow-up telephone calls. The total duration of follow-up is 24 weeks post-teaching session.

Previous interventions until 16/05/2013:
Following randomisation, both groups receive a two hour teaching session delivered to both parents in two parent families or one parent in single-parent families and telephone calls. Five groups of parents at each health unit (5 units) attend two hour teaching sessions (either sleep-

based or safety-based). Two telephone calls per week for two weeks support the parent leading the intervention by focusing on reinforcing the knowledge and skills obtained from the two-hour teaching session. After the six-week data collection point, the sleep group receives a pamphlet on managing infant safety and the safety group receives a pamphlet about managing infant sleep problems.

Experimental Group:
The teaching session for the intervention group and the follow-up phone calls, which were developed by Hall for the pilot study, will be delivered by PHNs who have been trained by the research team. This intervention aims to change parents' cognitions about areas, such as normal infant sleep, effects of inadequate sleep for infants and parents, setting limits around infant sleep, feeding infants to sleep, and infant sleep safety. It introduces behaviours parents can use to promote sleep self-initiation in infants. Parents receive instructions for completing charts so they can track their use of routines and controlled comforting and changes in infant sleep and settling. A videotaped recording of an infant in light and deep sleep, and a videotaped recording of an interview with parents about living with their infant's sleep problem will be shown. The session ends with a question and answer period. Parent handouts include: a paper copy of the scripted Power Point presentation, five copies of the weekly sleep-wake-feed charts and 10 copies of the controlled crying/comforting charts. To reinforce information and provide support for the parent leading the intervention, PHNs will make two telephone calls per week for two weeks. The calls will include questions to determine how best to provide support:
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1. How are parents managing?
2. Which strategies are they using to deal with the sleep problem?
3. What are the effects of those strategies on the infant and parents?
4. What, if any, difficulties are they experiencing?
PHNs will also provide a check list of points and standard responses to requests by family members for assistance beyond the sleep intervention.

The total duration of treatment is three weeks (one two-hour teaching session, and two weeks of twice weekly follow-up telephone calls. The total duration of follow-up is 24 weeks post-teaching session.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Significant infant sleep disturbance as measured with a composite measure, consisting of either the parent reporting a severe sleep problem, using the four-point sleep problem severity measure (no problem to severe problem), or mean actigraphic wakes of greater than two per night averaged over five nights at six weeks post-teaching session. These measures will be obtained at baseline, 6 weeks post-teaching session and 24 weeks post-teaching session.

Secondary outcome measures
Measured at 6 and 24 weeks post-teaching session:
1. Infants' averaged mean wakes over five nights by actigraphy
2. Parents' perceptions of sleep problems (using the four-point sleep problem severity measure)
3. Fatigue (using the Multidimensional Assessment of Fatigue Scale)
4. Depressed mood (using the Centre for Epidemiologic Studies Depression Measure)
5. Duration of infants' longest sleep periods (by actigraphy)
6. Parents quality of sleep (using the Pittsburgh Sleep Quality Index)
7. Quality of parental cognitions about infant sleep (using the Maternal Cognitions about Infant Sleep Questionnaire)
8. Costs for the intervention compared to the costs of parents using other sources of help (using resources consumed and unit prices for resources, including intervention costs)

Overall study start date
01/09/2009

Overall study end date
01/12/2011

Eligibility

Participant inclusion criteria
Infants:
1. Have no identified health problems
2. Between corrected ages of 5.5 and 8 months, either sex
3. Meet the American Academy of Sleep Medicine (AASM) sleep problem criteria (waking two or more times per night and/or waking lasting more than 20 minutes, occurring at least four nights per week for a minimum of three weeks)

Parents:
1. Biological or adoptive
2. Can read and speak English
3. Have access to a telephone
4. Are in single parent families or two parent families with both parents committing to the study

Participant type(s)
Patient

Age group

Child

Lower age limit
5.5 Months

Upper age limit
8 Months

Sex
Both

Target number of participants
720 participants (240 families with infant, mother and father)

Participant exclusion criteria
Infants:
1. Organic causes of sleep disruption
2. Developmental disability
3. Chronic neurological or respiratory conditions

Parents:
1. Diagnosed depression
2. Diagnosed sleep problems
3. Permanent night shift work

Recruitment start date
01/09/2009

Recruitment end date
01/12/2011

Locations

Countries of recruitment
Canada

Study participating centre
T. 201 2211 Wesbrook Mall
Vancouver
Canada
V6T 2B5

Sponsor information

Organisation

University of British Columbia (Canada)

Sponsor details
Office of Research Services
TEF III #102
6190 Agronomy Road
Vancouver, BC
Canada
V6T 1Z3

Sponsor type
University/education

Website
http://www.ubc.ca/

ROR
https://ror.org/03rmrcq20

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-94836)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

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	13/11/2015		Yes	No