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The TIPS (Tips for Infant and Parent Sleep) trial

Submission date	Recruitment status	[ ] Prospectively registered
03/07/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/07/2008	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/05/2013	Nervous System Diseases	

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
MCT-84658

Study information

Scientific Title
Tips for Infant and Parent Sleep: a randomised, blinded, parallel assignment trial

Acronym
TIPS

Study objectives
Primary question:
Compared to usual care, what is the effect of a behavioural-educational sleep intervention in the early postpartum on maternal nocturnal sleep?

Secondary question:
Compared to usual care, what is the effect of a behavioural-educational sleep intervention in the early postpartum on length of an infant's longest nocturnal sleep period?

Additional research questions will address the effects of a behavioural-educational sleep intervention in the early postpartum on: maternal nighttime awakenings, infant nighttime awakenings, maternal sleep disturbance, depressive symptomatology, maternal morning fatigue, and breastfeeding.

Please note that as of 04/03/2009 the anticipated end date in this record was amended; the previous date was as follows:
Initial anticipated end date: 01/12/2008

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committees of:
1. Sunnybrook Health Sciences Centre, Toronto approved on the 27th November 2007
2. St Michael's Hospital, Toronto approved on the 4th February 2008
3. University of Toronto approved on the 9th March 2007

Study design
Randomised, blinded (investigator, data analyst, research nurse), parallel assignment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Sleep disorders

Interventions
Experimental:
TIPS (45-minute behavioural-educational session with a Research Nurse [RN] in hospital, 20-page booklet, 3 phone calls at home in the postpartum).

Control:
Usual care (three phone calls at home to provide attention only).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Maternal nocturnal (9 pm - 9 am) sleep (in minutes) as measured at 6 and 12 weeks postpartum.

Secondary outcome measures
Infant's longest nocturnal (9 pm - 9 am) sleep period (in minutes) as measured at 6 and 12 weeks postpartum.

Overall study start date
30/05/2008

Completion date
15/04/2009

Eligibility

Key inclusion criteria
1. Women (single or partnered), no age limit
2. Have given birth for the first time
3. Have a singleton baby born at gestational age (GA) greater than or equal to 37 weeks
4. Have a baby described as healthy in the newborn examination
5. Live in the greater Toronto area
6. Plan to provide full time infant care for at least the first 12 weeks after birth
7. Women with previous miscarriages at less than 20 weeks GA are eligible if the most recent pregnancy resulted in a first child

Participant type(s)
Patient

Age group
Adult

Sex

Both

Target number of participants
234

Key exclusion criteria
1. Women or women whose partners have experienced stillbirth or perinatal death at greater than or equal to 20 weeks GA
2. Women whose partners have children from another relationship
3. Maternal or infant complications requiring prolonged hospital stay
4. Maternal chronic illness that is poorly controlled
5. Maternal use of medications that affect sleep (e.g. benzodiazepines)
6. Maternal (or partner, if they exist) drug or alcohol use beyond social use
7. Women (or partners, if one exists) with a diagnosed sleep disorder (e.g. sleep apnoea, narcolepsy)
8. Mother's partner, if one exists, is working night shifts
9. Mother unable to read or understand English
10. No telephone in the home
11. Involvement in another research study involving sleep

Date of first enrolment
30/05/2008

Date of final enrolment
15/04/2009

Locations

Countries of recruitment
Canada

Study participating centre
Faculty of Nursing
Toronto
Canada
M5T 1P8

Sponsor information

Organisation
University of Toronto (Canada)

Sponsor details
27 King's College Circle
Toronto

Canada
M5S 1A1

Sponsor type
University/education

Website
http://www.utoronto.ca/

ROR
https://ror.org/03dbr7087

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-84658)

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	20/03/2013		Yes	No