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Cues and Care: A trial of an intervention to promote mothers' ability to communicate with their very low birthweight infants

Submission date 29/05/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 29/05/2008	**Overall study status** Completed	
Last Edited 06/11/2019	**Condition category** Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Phyllis Zelkowitz

Contact details
Departement de Psychiatrie
Hopital General Juif SMBD
4333 Chemin de la Cote Ste Catherine
Montreal, Quebec
Canada
H3T 1E4
+1 514 340 8222 ext. 5258
phyllis.zelkowitz@mcgill.ca

Additional identifiers

Protocol serial number
MCT-79216

Study information

Scientific Title

A trial of a skills-based intervention to reduce maternal anxiety and improve developmental outcomes in very low birthweight infants

Acronym
Cues and Care Trial

Study objectives
Primary hypothesis:
The experimental group mothers will report lower levels of anxiety post-intervention compared to control group mothers.

Secondary hypotheses:
Compared to control group mothers, experimental group mothers will, in the immediate post-intervention period:
1. Have lower stress related to their infant's appearance and behaviour
2. Have lower stress related to their parental role restriction
3. Be more sensitive and responsive in interactions with their infant

At the 6-month follow-up:
4. Report less anxiety
5. Have lower perinatal post-traumatic stress
6. Exhibit greater sensitivity and responsivity in interactions with their infant

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Research Ethics Committee of Sir Mortimer B. Davis Jewish General Hospital-Mtl (Hôpital Général Juif Sir Mortimer B. Davis) on the 31st March 2006 (ref: CRO6-19).

Study design
Multicentre, two arm, randomised parallel trial with outcome assessor blinding.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anxiety in mothers of very low birthweight infants

Interventions
Experimental group:
Anxiety reduction techniques and sensitivity training, six sessions with an intervener, each lasting 60 - 90 minutes, for a total dose of 9 - 10 hours. The experimental intervention will be delivered over a six to eight week period.

Attention control group:
Provision of general information on infant care, six sessions with an intervener, each lasting 60 -

90 minutes, for a total dose of 9 - 10 hours. The control intervention will be delivered over a six to eight week period.

Contact for public queries:
Jenifer Chappell
Project Coordinator
Tel: +1 514 340 8222 ext. 3267
Email: jenifer.chappell@gmail.com

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Maternal state anxiety, immediately post-intervention at infant corrected age of 1 - 1.5 months.

Key secondary outcome(s))
1. Stress related to infant's appearance and behaviour in the Neonatal Intensive Care Unit (NICU), immediately post-intervention at infant corrected age of 1 - 1.5 months
2. Stress related to maternal role restriction, immediately post-intervention at infant corrected age of 1 - 1.5 months
3. Sensitivity of maternal behaviour, immediately post-intervention at infant corrected ages of 1 - 1.5 months and 6 months
4. Perinatal post-traumatic stress, immediately post-intervention at infant corrected ages of 1 - 1.5 months and 6 months
5. Postpartum depression, infant corrected age of 1 - 1.5 months and at 6 months corrected age
6. Infant cognitive and motor development, when the infant is of 6 months corrected age

Completion date
30/09/2009

Eligibility

Key inclusion criteria
1. Infant birthweight less than 1500g
2. Mother can speak and read either English or French
3. Mother able to sign informed consent form
4. Family resides withing a 90 minute drive of participating hospitals

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Mother will not be caring for the infant after discharge (e.g. due to foster placement or adoption)
2. Infant is in a highly unstable medical condition that is likely to result in death, has a major congenital anomaly, or is known to have a major sensory handicap (e.g. blindness)
3. Infant is likely to be transferred or discharged in less than four weeks
4. Multiple birth (twins, triplets)

Date of first enrolment
01/05/2006

Date of final enrolment
30/09/2009

Locations

Countries of recruitment
Canada

Study participating centre
Departement de Psychiatrie
Montreal, Quebec
Canada
H3T 1E4

Sponsor information

Organisation
Sir Mortimer B. Davis Jewish General Hospital (Hôpital Général Juif Sir Mortimer B. Davis) (Canada)

ROR
https://ror.org/056jjra10

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-79216)

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?
Protocol article	study protocol	26/09/2008		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes