

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	<input type="checkbox"/> Prospectively registered
Registration date 29/05/2008	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 06/11/2019	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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
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 responsiveness 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:

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Project Coordinator

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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 within 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