

Baby Business: the first few months of life

Submission date 17/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 14/07/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/02/2021	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Harriet Hiscock

Contact details
Royal Children's Hospital
Centre for Community Child Health
Flemington Road
Parkville
Australia
3052
+61 (0)3 9345 6910
harriet.hiscock@rch.org.au

Additional identifiers

Protocol serial number
28130B

Study information

Scientific Title
The impact of a brief universal parenting program to prevent early infant sleep and cry problems and associated parental depression: a randomised controlled trial

Study objectives

It is hypothesised that in comparison to the control group, the Baby Business intervention will result in fewer infant crying and sleeping problems, and secondarily, will result in reduced post-natal depression.

It is also predicted that this in turn, will reduce health service costs related to management of infant crying and sleep problems.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Royal Children's Hospital Human Research Ethics Committee approved on the 5th January 2009 (ref: 28130B)
2. Department of Education and Early Childhood Development Early Childhood Research Committee approved on the 10th December 2009

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Early infant sleep and cry problems

Interventions

Maternal child health nurses will approach all parents at the first postnatal home visit (which usually takes place at infant age 1 - 2 weeks) and invite them to participate. All participating primary care-givers will complete a baseline questionnaire including socio-demographic data, infant details (birth weight, birth order, gender, date of birth), feeding method (breast, formula, combination of breast/formula) and whether the infants sleep or crying is a problem. Both parents will be encouraged to take part in the study.

Baby Business Intervention:

Parents in the intervention group will be offered a brief parenting intervention in addition to their usual post-natal care. The intervention will consist of:

1. A parenting booklet and DVD
2. A telephone consultation when the infant is 3 - 7 weeks old, followed by
3. A group parenting session at a local maternal child health centre for all parents when their infant is 8 - 12 weeks old

The intervention will focus on normal infant sleep and crying and ways to encourage infants to self-soothe. It will aim to address all concerns raised by parents. Appropriate referrals to other services will be organised if necessary. The intervention will be performed by a member of the research team who is a health professional with expertise in managing maternal and infant health issues in the first few months of life.

Control Group:

Parents in the control group will receive usual post-natal health care.

All parents will complete follow up questionnaires addressing infant sleep and cry problems and parental wellbeing when their infants turn 4 and 6 months of age.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Infant sleep and crying problems as reported by the parents and as recorded in a 72 hour baby diary.

Key secondary outcome(s)

1. Postnatal depression (Edinburgh Postnatal Depression Scale [EPDS])
2. Costs associated with seeking external help for infant sleep and cry problems and parental depression

Both will be measured when the babies reach 4 and then 6 months of age.

Completion date

15/06/2011

Eligibility**Key inclusion criteria**

Families of newborn infants in the local government areas of Yarra, Brimbank and Wyndham (all based around Melbourne, Australia).

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

Total final enrolment

781

Key exclusion criteria

1. Parents of infants who were born at less than 32 weeks gestation
2. Parents of infants with a severe health problem

3. Parents who cannot read, write or speak English well enough to complete questionnaires, a telephone call and a group session

Date of first enrolment

15/02/2010

Date of final enrolment

15/06/2011

Locations

Countries of recruitment

Australia

Study participating centre

Royal Children's Hospital

Parkville

Australia

3052

Sponsor information

Organisation

Murdoch Childrens Research Institute (MCRI) (Australia)

ROR

<https://ror.org/048fyec77>

Funder(s)

Funder type

Government

Funder Name

Department of Education and Early Childhood Development (Australia)

Funder Name

The Scobie and Claire MacKinnon Trust (Australia)

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	01/02/2014	26/02/2021	Yes	No
Protocol article	protocol	06/02/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes