

# Baby Business: the first few months of life

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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Quality of life

**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**

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 measure**

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

### **Secondary outcome measures**

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.

### **Overall study start date**

15/02/2010

### **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

**Age group**

Child

**Sex**

Both

**Target number of participants**

750

**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)

**Sponsor details**

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### Sponsor type

Research organisation

### Website

<http://www.mcri.edu.au>

### 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

### 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?
<a href="#">Protocol article</a>	protocol	06/02/2012		Yes	No
<a href="#">Results article</a>	results	01/02/2014	26/02/2021	Yes	No