

# Impact of an infant sleep parenting intervention at age 6 months on infant sleep problems at ages 6 to 12 months and maternal psychological and physical wellbeing

**Submission date**

07/09/2004

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**

04/11/2004

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

28/01/2013

**Condition category**

Mental and Behavioural Disorders

☐ Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

**Study website**

[http://www.rch.org.au/ccch/research.cfm?doc\\_id=10629](http://www.rch.org.au/ccch/research.cfm?doc_id=10629)

## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

EudraCT/CTIS number

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

NHMRC 237120; ACTRN12607000036415

## **Study information**

### **Scientific Title**

Impact of an infant sleep parenting intervention at age 6 months on infant sleep problems at ages 6 to 12 months and maternal psychological and physical wellbeing: a cluster controlled trial

### **Acronym**

ISS - Infant Sleep Study / KIDS - Kids Sleep Study

### **Study objectives**

Sleep problems (e.g. frequent night waking) in babies aged 6 to 12 months and impact of treating problems on maternal psychological and physical wellbeing.

1. A brief behavioural intervention delivered by Maternal and Child Health (MCH) nurses will lead to the following outcomes:

1.1. Decreased prevalence of infant sleep problems (3 months after treatment)

1.2. Improved infant sleep patterns (3 months after treatment)

1.3. Improved wellbeing for mothers with initial scores indicative of postnatal depression (3 months after treatment)

1.4. Sustained improvement in maternal wellbeing and infant sleep patterns (5 months after treatment)

2. A structured training and education package emphasising simple behavioural management strategies will lead to a sustained increase in knowledge, competence and confidence of MCH nurses in addressing sleep problems in 8-10 month infants

Added 23/06/10:

KIDS: Kids Sleep Study: Long-term outcomes and impacts on mental and physical health at age 6 of a randomised controlled trial of a behavioural sleep intervention delivered at 8-months - A follow up study, which ran from 01/04/09 to 31/12/09, was added to this trial called KIDS (all updates pertaining to the follow up study will be headed with the title KIDS) with the following hypotheses:

In a cohort of children drawn from the pre-existing Infant Sleep Study RCT, we hypothesise that:

1. At child age 6 there will be no meaningful differences between intervention and control groups in:

1.1. Current child sleep problems

1.2. Child emotional and behaviour problems

1.3. Maternal depression

1.4. Child stress as measured by salivary cortisol and glycosylated haemoglobin and

1.5. Disengaged neglectful parenting style and childrens disinhibited attachment; proxies for child attachment to the primary caregiver

2. Overweight/obesity at age 6 will be predicted by:

2.1. Group membership (i.e. intervention versus control groups), or

2.2. Shorter sleep duration at ages 12 and/or 24 months, regardless of group membership

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics in Human Research Committee, Royal Childrens Hospital (ref: EHRC 23067B, for KIDS follow up ref: EHRC 28137F)

### **Study design**

Randomised controlled trial with long term follow up

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Other

### **Study type(s)**

Treatment

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

ISS: Paediatric sleep problems

KIDS: Long-term effects of a behavioural sleep intervention

### **Interventions**

Cluster randomised controlled trial, cluster at the level of the well-child centre. Masking occurred at randomisation, with group allocation concealed from researchers and participants until allocation was complete.

Arm A: Behavioural interventions to manage frequent night waking and/or difficulty settling to sleep including controlled crying, camping out and advice on how to manage overnight feeding and dummies (pacifiers). Strategies were delivered by maternal and child health nurses over 2 to 3 visits (initial visit 30-60 minutes, subsequent visits 10-15 minutes).

Arm B: Usual care from maternal and child health nurses who provide a universal and free surveillance service to Melbourne families in the first 5 years of life (active control).

KIDS study contact details:

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**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Maternal report of an infant sleep problem at ages 10 and 12 months

KIDS: Child emotional and behaviour problems

**Secondary outcome measures**

Maternal psychological and physical wellbeing, maternal sleep quantity and quality at ages 10 and 12 months

KIDS: Child stress, child sleep habits and problems, maternal psychological wellbeing and parenting style

**Overall study start date**

10/10/2003

**Completion date**

31/08/2004

## **Eligibility**

**Key inclusion criteria**

Families recruited were attending community well-child clinics across six Melbourne local government areas when infants were 4 months postpartum in October/November 2003. Families were recruited from a broad sociodemographic sample. Infants whose parents reported a problem with their sleep at 7 - 8 months were then eligible to take part in this trial.

KIDS: All families who participated in the original Infant Sleep Study (n=328)

**Participant type(s)**

Patient

**Age group**

Child

**Sex**

Both

**Target number of participants**

Target sample size 270. Recruitment status achieved N = 328 (KIDS: Target sample size 200. Recruitment status achieved N = 225 of eligible 326)

**Key exclusion criteria**

Mothers with insufficient English to complete brief written questionnaires

KIDS: Children diagnosed with intellectual disability or autism since turning 2 years old (n=2)

**Date of first enrolment**

10/10/2003

**Date of final enrolment**

31/08/2004

**Locations****Countries of recruitment**

Australia

**Study participating centre**

Centre for Community Child Health

Melbourne

Australia

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**Sponsor information****Organisation**

Murdoch Children's Research Institute (Australia)

**Sponsor details**

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**Sponsor type**

Research organisation

**ROR**

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

## **Funder(s)**

### **Funder type**

Research council

### **Funder Name**

National Health and Medical Research Council (NHMRC) (Australia) (ref: 237120)

### **Alternative Name(s)**

NHMRC

### **Funding Body Type**

Government organisation

### **Funding Body Subtype**

National government

### **Location**

Australia

### **Funder Name**

KIDS:

### **Funder Name**

Foundation for Children (Australia) - Project Grant 2009

### **Funder Name**

University of Melbourne (Australia) - Melbourne Research Scholarship

## **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="#">Results article</a>	results	01/11/2007		Yes	No
<a href="#">Results article</a>	results	01/09/2008		Yes	No
<a href="#">Results article</a>	results	01/06/2011		Yes	No
<a href="#">Results article</a>	results	01/09/2012		Yes	No
<a href="#">Results article</a>	results	01/10/2012		Yes	No