

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	<input type="checkbox"/> Prospectively registered
Registration date 04/11/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/01/2013	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

KIDS: Child emotional and behaviour problems

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Sex

All

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
3052

Sponsor information

Organisation

Murdoch Children's Research Institute (Australia)

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)

National Health and Medical Research Council, Australian Government, NHMRC National Health and Medical Research Council, 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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2007		Yes	No
Results article	results	01/09/2008		Yes	No
Results article	results	01/06/2011		Yes	No
Results article	results	01/09/2012		Yes	No
Results article	results	01/10/2012		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes