

Preventing mental health problems in children

Submission date 20/04/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 29/06/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 31/01/2019	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims.

Behaviour and emotional problems affect one in seven Australian children. These problems include aggression, hyperactivity, disobedience, anxiety, social withdrawal and depression. Around 50% of preschool children's problems continue through the childhood years. Since 2002, the Toddlers Without Tears (TWT) program has aimed to stop children from developing behaviour and emotional problems using a brief group parenting program. Families in Mind combines this brief program with a targeted treatment to examine whether combining the two programs is more effective than one program alone.

Families in Mind has been designed by child doctors, child psychologists and maternal and child health nurses. It is a three-arm trial:

1. Combined arm: a brief group parenting program (modelled on TWT) plus a targeted one-on-one family support program
2. Targeted arm: a one-on-one family support program
3. Usual care arm: no extra programs but families can access help from usual services

Families in Mind is suitable for all families with young children, and uses parenting handouts, group discussion, and video examples.

The aims of the study are to:

Help parents learn how to encourage positive toddler behaviour, and reduce aggressive and anxious behaviours

Understand how child behaviour and emotional problems develop in the first six years of life (from infancy)

Prevent young children from developing behaviour and emotional problems as they grow

Measure the economic costs of delivering this parenting program, including the targeted one-on-one support in the community

Who can participate?

English-speaking families with a healthy child attending their routine, 8-month, free Maternal and Child Health visit in one of nine Local Government Areas in Melbourne, Australia.

What does the study involve?

In 2010, 1500 families who choose to take part are randomly divided into three groups:

Combined, Targeted and Usual care. Families in the combined arm are invited to attend three parenting groups run in their local area by Maternal and Child Health Nurses when their children turn 15, 18 and 24 months old. These groups are based on the Toddlers Without Tears study and

focus on parenting practices to prevent behaviour problems. In 2012, all families are followed up as their children turn 2 years old. Families in the Combined and Targeted arms who need extra support are offered the targeted one-on-one support program. In 2013, all families are followed up as their children turn 3-4 years of age. In 2014, all families are followed up as their children turn 4-5 years of age.

What are the possible benefits and risks of participating?

Parents receiving one or more of the treatments may benefit from improved parenting skills, child behaviour and mental health at child age 3 and 4-5 years. We do not expect there to be any risks associated with taking part.

Where is the study run from?

The Murdoch Childrens Research Institute and The Royal Childrens Hospital, Melbourne, Australia.

When is the study starting and how long is it expected to run for?

Recruitment began in August 2010 and the study is expected to end in September 2015

Who is funding the study?

NHMRC Partnership Grant 546525

Who is the main contact?

Associate Professor Harriet Hiscock

harriet.hiscock@rch.org.au

Contact information

Type(s)

Scientific

Contact name

Dr Harriet Hiscock

Contact details

Centre for Community Child Health
Royal Children's Hospital Melbourne
Flemington Road
Parkville, Victoria
Melbourne
Australia
3052

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Harriet.Hiscock@rch.org.au

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Preventing mental health problems in children: a population-based cluster controlled trial

Study objectives

This population-level randomised control trial aims to prevent behavioural and emotional problems from developing in pre-school children. The study has three arms: (A) combined universal-targeted approach; (B) targeted approach; and (C) usual care. We hypothesise that:

1. Each of the combined universal-targeted approach (A) and the targeted only approach (B) will be more effective and have greater population reach than current primary care services (C)
2. Uptake of the targeted prevention component for families where the child is at "high risk" of behavioural problems will be greater under the combined universal-targeted approach (A) than under the targeted only approach (B)

Ethics approval required

Old ethics approval format

Ethics approval(s)

Royal Children's Hospital Melbourne Ethics and Research Board approved on the 17/06/2010 (ref: 29144A)

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Not available in web format, please contact Ms Kate Lycett [kate.lycett@mcri.edu.au] to request a patient information sheet

Health condition(s) or problem(s) studied

Child externalising and internalising problems

Interventions

Arm A: All families in this group will be offered a parenting program (universal approach). This involves attending a parenting session when their child is 15, 18 and 24 months old. If at about 2 years of age a child is having behaviour or emotional difficulties or a family feels stressed, a one-on-one family support program (targeted approach) will also be offered.

Arm B: Some families in this group will be offered one-on-one family support (targeted approach). Families will be offered this service if their child is having behaviour or emotional difficulties at about age 2 or if the family feels stressed.

Arm C: Families in this group will only be offered usual care by their maternal child health nurse

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Current primary outcome measures as of 30/08/2013:

Child externalising and internalising diagnoses/symptoms at age 3 and 4-5 years.

Previous primary outcome measures:

Child externalising and internalising diagnoses/symptoms and a measure of parent behaviour (nurturing/harsh discipline) at ages 3, 4 and 5.

Secondary outcome measures

Current secondary outcome measures as of 30/08/2013:

Parenting practice (harsh discipline, nurturing), parent mental health and economic evaluation at age 3 and 4-5 years.

Previous secondary outcome measures:

Parenting practices, parent mental health, and economic evaluation at ages 3, 4 and 5.

Overall study start date

01/08/2010

Completion date

30/09/2015

Eligibility

Key inclusion criteria

Eligible participants are parents (primarily mothers) of 8 month old babies in 9 Melbourne local government areas. Parents will be invited to join the study between August and October 2010. We expect an even distribution of girls and boys in the study.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Target sample size is 1475

Key exclusion criteria

1. Parents with insufficient English to participate
2. Parents with babies with a major health condition

Date of first enrolment

01/08/2010

Date of final enrolment

30/09/2015

Locations

Countries of recruitment

Australia

Study participating centre

Centre for Community Child Health

Melbourne

Australia

3052

Sponsor information

Organisation

National Health and Medical Research Council (NHMRC) (Australia)

Sponsor details

Level 1, 16 Marcus Clarke Street

Canberra

Australia

2601

Sponsor type

Research council

Website

<http://www.nhmrc.gov.au/>

ROR

<https://ror.org/011kf5r70>

Funder(s)

Funder type

Research council

Funder Name

National Health and Medical Research Council (NHMRC) (Australia) (ref: 546525)

Alternative Name(s)

NHMRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Australia

Funder Name

Department of Human Services (Australia) - Mental Health

Funder Name

Department of Human Services (Australia) - Primary Health

Funder Name

Municipal Associations of Victoria (Australia)

Funder Name

Department of Education and Early Childhood (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?
Protocol article	protocol	08/06/2012		Yes	No
Results article	results	01/01/2018	31/01/2019	Yes	No