

Preventing early anxiety disorders

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
18/01/2010	No longer recruiting	<input checked="" type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
18/03/2010	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
17/06/2021	Mental and Behavioural Disorders	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Preventing early internalising problems in the preschool setting: a randomised controlled trial

Study objectives

This population-level randomised trial aims to test a preventive parenting program in the preschool setting for children systematically screened as at-risk of internalising problems due to temperamental inhibition. We hypothesise that:

1. Children whose parents enter the program will do better 12 and 24 months after baseline (the first two years of school for most) than control children on the study outcomes:
 - 1.1. Fewer children with internalising disorders
 - 1.2. Lower mean scores on early child internalising symptoms
 - 1.3. Lower mean scores on harsh and overprotective parenting
 - 1.4. Lower mean scores on parent internalising problems
2. The prevention program will be acceptable and cost-effective

We will also examine differential effectiveness according to parent mental health and family level of disadvantage.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Royal Childrens Hospital Melbourne Ethics and Research Committee pending approval as of 20/01/2010 (ref: EHRC 21942). Estimated approval date is September 2010.

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Child internalising (anxiety) problems

Interventions

Masking occurs at randomisation, with group allocation concealed from researchers and participants until allocation is complete.

Arm A:

Six-session group parenting program, delivered in the local community by an early childhood professional, focusing on ways to develop the child's bravery skills by reducing overprotective parenting interactions.

Arm B:

Usual care from the preschool, early childhood and health services in the community.

Total duration of treatment: 2 - 3 months (6 x 90-minute group parenting sessions)

Total duration of follow-up: 24 months post-baseline

Intervention Type

Behavioural

Primary outcome(s)

Child internalising diagnoses and symptoms at 12 and 24 months post-baseline.

Key secondary outcome(s)

Evaluated at 12 and 24 months post-baseline:

1. Parenting practices
2. Parent mental health
3. Economic evaluation

Completion date

30/04/2014

Eligibility

Key inclusion criteria

1. Parents of preschool children in their year before starting school in 2011
2. In four Melbourne local government areas
3. Children screened as temperamentally inhibited, either sex

Participant type(s)

Other

Healthy volunteers allowed

No

Age group

Child

Sex

All

Total final enrolment

545

Key exclusion criteria

Parents with insufficient English to participate

Date of first enrolment

01/02/2010

Date of final enrolment

30/04/2014

Locations

Countries of recruitment

Australia

Study participating centre
Centre for Community Child Health
Parkville, Victoria
Australia
3052

Sponsor information

Organisation

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

ROR

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

Funder(s)

Funder type

Research council

Funder Name

National Health and Medical Research Council (NHMRC) (Australia) (ref: 607302)

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

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	01/08/2018		Yes	No
Results article	2-year follow-up results	01/08/2020	30/11/2020	Yes	No
Results article	follow-up results	01/06/2021	17/06/2021	Yes	No
Protocol article	protocol	05/01/2011		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes