

Preventing early anxiety disorders

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

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

Secondary outcome measures

Evaluated at 12 and 24 months post-baseline:

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

Overall study start date

01/02/2010

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

Age group

Child

Sex

Both

Target number of participants

Target sample size is 525

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)

Sponsor details

Level 1

16 Marcus Clarke St

Canberra, ACT

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: 607302)

Alternative Name(s)

NHMRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

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	05/01/2011		Yes	No
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