ISRCTN30996662 https://doi.org/10.1186/ISRCTN30996662

Preventing early anxiety disorders

Submission date	Recruitment status	[_] Prospectively registered
18/01/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/03/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] 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

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Additional identifiers

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.

Primary study design
Interventional

Study design
Randomised controlled trial

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