

Preventing preschool externalising behaviour problems: A cluster controlled trial evaluating the 'Toddlers Without Tears' parenting program delivered at age 8-15 months

Submission date 06/09/2004	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 26/10/2009	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
ACTRN12606000239561

Study information

Scientific Title

Acronym

TWT - Toddlers Without Tears

Study objectives

Preschool child externalising behaviour problems including aggression, opposition and hyperactivity.

1. At age 18 months:

1.1. Decreased incidence of externalising behaviours

1.2. Decreased prevalence of harsh and abusive parenting

1.3. Increased prevalence of warm and developmentally appropriate parenting

1.4. Decreased prevalence of maternal depression/anxiety

2. At age 24 months:

2.1. Sustained improvement in child behaviour, parenting and maternal wellbeing

3. An increase in knowledge, competency and confidence of Maternal and Child Health nurses in delivering anticipatory guidance for behaviour problems in young toddlers

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Ethics in Human Research Committee (EHRC) (ref: 24020A)

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Behavioural disorders

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: Parenting program (one individual 15-minute and two 2-hour group sessions) about normal child development, ways to encourage desirable behaviour and ways to manage misbehaviour in toddlers. Strategies derived from systematic reviews of parenting programs for treating established child externalising behaviour problems. Program delivered by maternal and child health nurses and co-facilitated by parenting experts.

Arm B: Usual care provided by nurses at well-child visits (active control)

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Primary outcome 1: Parent-reported child behaviour problems on the Child Behaviour Checklist (Achenbach & Rescorla, 2000). Measured at 18 months, 24 months and 3 years.

Primary outcome 2: Parent-reported parenting practices on the Parent Behaviour Checklist (subscales: developmental expectations, nurturance, harsh discipline) (Fox, 1994). Measured at 18 months, 24 months and 3 years.

Primary outcome 3: Parent-reported mental health on the Depression Anxiety Stress Scales (Lovibond & Lovibond, 1995). Measured at 18 months, 24 months and 3 years.

Key secondary outcome(s)

Economic evaluation (cost consequences) of cost of delivering the intervention and costs of other services used by families for either the child's behaviour and/or the mother's mental health.

Timepoint: At 18, 24 and 36 months.

Completion date

30/06/2006

Eligibility**Key inclusion criteria**

Eligible participants were parents of children aged 6 months attending community well-child clinics across 6 Melbourne local government areas during August/September 2004. Families were recruited from a broad sociodemographic sample.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

Key exclusion criteria

Parents with insufficient English to attend a parenting group and complete brief written questionnaires.

Date of first enrolment

01/12/2001

Date of final enrolment

30/06/2006

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

Charity

Funder Name

Philanthropic Organisation (Australia)

Funder Name

William Buckland Foundation (Australia)

Funder Name

Telstra Community Development Fund (Australia)

Results and Publications

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?
Results article	results	09/02/2008		Yes	No
Results article	results	01/03/2010		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes