

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

<b>Submission date</b> 06/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 04/11/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 26/10/2009	<b>Condition category</b> 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

## Study website

[http://www.rch.org.au/emplibrary/ccch/Todd\\_tears.pdf](http://www.rch.org.au/emplibrary/ccch/Todd_tears.pdf)

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Prevention

**Participant information sheet**

## **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 measure**

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.

## **Secondary outcome measures**

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.

## **Overall study start date**

01/12/2001

## **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

**Age group**

Child

**Sex**

Both

**Target number of participants**

Target sample size 370. Recruitment status achieved n = 734

**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)

**Sponsor details**

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**Sponsor type**

Research organisation

**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

**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?
<a href="#">Results article</a>	results	09/02/2008		Yes	No

[Results article](#)

results

01/03/2010

Yes

No