

Anxiety in young children: A randomised controlled trial of a new cognitive-behaviourally based parenting intervention

Submission date 12/04/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/06/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 23/02/2011	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

Study website

<http://www.psych-sci.manchester.ac.uk/pacmantrial/>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

G108/604

Study information

Scientific Title

Acronym

PACMAN trial (Parenting for Anxious Children - Manchester)

Study objectives

Participants randomised to receive a new cognitive-behaviourally based parenting intervention will exhibit greater reductions in anxiety disorders and internalising symptoms than:

- a. Those who have been in a waiting list control group, after the end of the intervention period (10 weeks)
- b. Those who were on the waiting list, and subsequently received treatment as usual at 12 months follow-up

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Taking part information is found in <http://www.psych-sci.manchester.ac.uk/pacmantrial/takingpart/>

Health condition(s) or problem(s) studied

Anxiety Disorders

Interventions

Experimental intervention: 10 week course of 2-h group sessions for parents. Content is cognitive-behaviourally based parenting advice, focussing on gentle and consistent discipline, relationship building, and techniques to manage worry and fear.

Control intervention: 10 weeks wait list, followed by treatment as usual.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

The primary outcome point is after 10 weeks participation in the trial, comparing those who have received the new intervention, and those who have remained on a waiting list. The primary outcome measure will be parent report of internalising symptoms on the Child Behavior Checklist.

Secondary outcome measures

The secondary outcome point is after 12 months in the trial where those who received the new intervention, and those who remained on a waiting list for at least 10 weeks before receiving treatment as usual will be compared. The secondary outcome measures are teacher report of internalising symptoms on the Child Behavior Checklist teacher report form; and DSM-IV Anxiety Disorder diagnosis.

Overall study start date

31/03/2005

Completion date

30/06/2008

Eligibility

Key inclusion criteria

Families of anxious children aged under 10 years. Patients will be included in the trial if they score at or above the suggested clinical cut-off for an internalising disorder on the child behaviour checklist (the primary outcome measure). However, to ensure that all participants are of clinical severity, they must also have a Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) diagnosis of an anxiety disorder, assessed by the Anxiety Disorders Interview Schedule for Children (not including specific phobia, obsessive compulsive disorder, post-traumatic stress disorder/acute stress disorder, anxiety due to a general medical condition, or substance induced anxiety disorder). Participants will not be excluded on the grounds of other comorbid conditions.

Participant type(s)

Patient

Age group

Child

Upper age limit

10 Years

Sex

Both

Target number of participants

72. Added 07/09/09: referrals are no longer accepted.

Key exclusion criteria

Parents or children with moderate to severe learning disabilities will not be included in the study. Children whose parents do not have adequate English to benefit from the group format of the intervention will not be included.

Date of first enrolment

31/03/2005

Date of final enrolment

30/06/2008

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

School of Psychological Sciences

Manchester

United Kingdom

M13 9PL

Sponsor information**Organisation**

University of Manchester (UK)

Sponsor details

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Sponsor type

University/education

ROR

<https://ror.org/027m9bs27>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK) G108/604

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?
Results article	results	01/03/2011		Yes	No