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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

Registration date
30/06/2005

Overall study status
Completed

Last Edited
23/02/2011

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))

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.

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

Healthy volunteers allowed
No

Age group
Child

Upper age limit
10 years

Sex
All

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
United Kingdom

England

Study participating centre
School of Psychological Sciences
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
University of Manchester (UK)

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Research council

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

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	01/03/2011		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes

Study website	Study website	11/11/2025	11/11/2025	No	Yes