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Overcoming your child's fears and worries: a self-help guide for childhood anxiety disorders

Submission date
06/10/2011

Recruitment status
No longer recruiting

Registration date
22/11/2011

Overall study status
Completed

Last Edited
03/12/2013

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Anxiety problems in childhood are common and can cause problems at home, in school and with friendships. Talking treatments based on cognitive-behaviour therapy (CBT) for childhood anxiety problems are known to work well in many cases, but accessing trained therapists can be difficult. We aim to investigate results obtained following two forms of guided CBT self-help, delivered via parents, in comparison to results of a wait list control group (the control group does not receive CBT).

Who can participate?
Participants are children aged 7-12 years referred to Berkshire Child Anxiety Clinic from across Berkshire (UK), who are experiencing significant anxiety problems (and meet criteria for an anxiety disorder) and their parent(s)/carer(s).

What does the study involve?
We are comparing two versions of the guided CBT self-help intervention (full and less intense) to a wait-list control group. The full version involves four face to face sessions with a therapist and four telephone review sessions; the less intense version involves two face to face and two telephone review sessions. The content of the sessions focuses in helping parents to help their child overcome their fears and worries using cognitive-behavioural principles.

What are the possible benefits and risks of participating?
Many children are expected to make significant gains in relation to their anxiety difficulties. No side-effects from treatment are anticipated.

Where is the study run from?
The Berkshire Child Anxiety Clinic, a joint service delivered across Berkshire (UK), by Berkshire Healthcare NHS Foundation Trust and the University of Reading.

When is the study starting and how long is it expected to run for?
The study started in April 2008 and the anticipated end date is December 2012.

Who is funding the study?
National Institute of Health Research, Research for Patient Benefit (UK).

Who is the main contact?
Professor Peter Cooper
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Contact information

Type(s)
Scientific

Contact name
Prof Peter Cooper

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
v06.02.2008

Study information

Scientific Title
Overcoming your child's fears and worries: a randomised controlled trial of guided self-help for childhood anxiety disorders

Acronym
Overcoming

Study objectives
In a randomised controlled trial of childhood anxiety (in the absence of a current maternal anxiety disorder) the principal research questions are:
1. Does full guided self-help CBT lead to a reduction in anxiety disorder diagnoses, in comparison to a wait-list control?
2. Does less intense guided self-help CBT lead to a reduction in anxiety disorder diagnoses, in comparison to a wait-list control?

Secondary research questions:
3. Does full guided self-help Cognitive behaviour therapy (CBT) lead to a reduction in anxiety symptoms, in comparison to a wait-list control?
4. Does less intense guided self-help CBT lead to a reduction in anxiety symptoms, in comparison to a wait-list control?
5. Are specific parenting practices (over involvement, fear expression) and thinking styles (expectations about child competency) associated with child treatment outcome (symptoms/ diagnosis)?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Berkshire Research Ethics Committee approved on 16 November 2007, ref: 07/H0505/157

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Child anxiety disorder

Interventions
Guided Cognitive Behaviour Therapy (CBT) self-help delivered via parents:
1. 8 sessions (4 face to face, 4 telephone)
2. 4 sessions (2 face to face, 2 telephone)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

1. Clinical Global Impressions of Improvement (CGI-I) (Much / Very much improved or not)
2. Anxiety Disorders Interview Schedule for DSM IV (child and parent versions) (ADIS-C/P) (Child free of primary anxiety disorder or not)

Secondary outcome measures
1. Child anxiety symptoms and impact (SCAS, Spence, 1998- child/parent/teacher report; CAIS, Langley et al., 2004 - child/parent report)
2. Parental interactive behaviours and cognitions as assessed by interview and observations

Overall study start date
25/04/2008

Completion date
30/12/2011

Eligibility

Key inclusion criteria
1. Aged 7 to 12 years
2. Primary diagnosis of Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) generalised anxiety disorder, social phobia, separation anxiety disorder, panic disorder /agoraphobia or specific phobia
3. Parent / primary carer attends treatment

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
195

Key exclusion criteria
Child:
1. Significant physical or intellectual impairment (including autistic spectrum disorders)
2. Current prescription of psychotropic medication (or, if psychotropic medication is prescribed, it should have been at a stable dose for at least one month with agreement to maintain that dose throughout the study)

Parent(s):
1. Current maternal DSM-IV anxiety disorder
2. Significant intellectual impairment
3. Severe comorbid disorder (e.g. severe major depressive disorder, psychosis, substance /alcohol dependence)
4. Prescription of psychotropic medication (or, if psychotropic medication is prescribed, it should have been at a stable dose for at least one month with agreement to maintain that dose throughout the study)

Date of first enrolment
25/04/2008

Date of final enrolment
30/12/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Psychology and Clinical Language Sciences
Berkshire
United Kingdom
RG6 6AL

Sponsor information

Organisation
University of Reading (UK)

Sponsor details
c/o Dr M J Proven
Research and Enterprise Services
Reading
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Sponsor type
Research organisation

Website

http://www.reading.ac.uk

ROR
https://ror.org/05v62cm79

Funder(s)

Funder type
Government

Funder Name
Medical Research Council (MRC) (UK) (ref: G0802326)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/12/2013		Yes	No