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Guided self-help for childhood anxiety problems: a comparison with usual care

Submission date
13/03/2012

Recruitment status
No longer recruiting

Registration date
13/03/2012

Overall study status
Completed

Last Edited
22/05/2017

Condition category
Mental and Behavioural Disorders

[X] 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 difficulties at home, in school and with friendships. We want to compare 2 treatments for children with anxiety problems, a talking treatment called 'guided Cognitive Behavioural Therapy (CBT) self-help for parents, with a common treatment that children receive primary care services called Solution Focused Brief Therapy (SFBT), to see which works best to help children become less anxious, and which treatment is most cost-effective.

Who can participate?
Participants are children aged 5-12 years referred to the Primary Child and Adolescent Mental Health Services (PCAMHS) from across Oxfordshire, UK, who are experiencing significant anxiety problems and their parent(s)/carer(s).

What does the study involve?
There is an initial visit with a researcher to talk to both the child and parents. If the child's main problem is anxiety, the child is allocated randomly to 1 of the 2 treatment groups. For both groups the treatment sessions will take place over 8 weeks. Treatment of childen in the guided CBT self-help group involves four face to face sessions with a therapist and four telephone review sessions, all with the parents, and the treatment in the Solution Focused Brief Therapy involves an initial and a final session with a therapist and child and parents, and 4 sessions in between with just the therapist and child. There are 2 further assessments after treatment (one just after treatment and another 6 months later) with a researcher to see how effective the treatment has been. All sessions take place in the family home unless this is difficult, in which case an alternative site is found.

What are the possible benefits and risks of participating?
Many children are expected to significantly reduce their anxiety levels. No side-effects from treatment are anticipated.

Where is the study run from?
The study involves all the 4 PCAMHS teams in Oxfordshire which are based at Banbury, Abingdon, Witney and Oxford city centre, and also the School of Psychology and Clinical Language Sciences at the University of Reading.

When is the study starting and how long is it expected to run for?
December 2011 to December 2013

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11481

Study information

Scientific Title
The treatment of child anxiety in primary care via guided CBT self-help: a randomised controlled trial

Study objectives
The study is a randomised controlled trial to evaluate the efficacy and cost-effectiveness of guided CBT self-help for child anxiety within PCAMHS across Oxfordshire. Participants, parents of clinically anxious children aged 5-12 years, will be randomly allocated to either the guided CBT self-help condition or to PCAMHS standard care (SFBT) in order to establish whether the guided CBT self-help approach offers benefits in comparison to the intervention families usually receive within PCAMHS. The study will assess whether guided CBT self-help delivers improved outcomes (i.e., reduction of symptoms) in comparison to standard care; whether these differences are maintained six months post-treatment, and whether self-help significantly lowers the costs associated with child anxiety.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. NHS Health Research Authority, South Central - Berkshire, 21/11/2011, ref: 11/SC/0472
2. The University of Reading Ethics Committee, 27/01/2012

Study design
Randomised interventional treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Anxiety

Interventions
Guided CBT Self-help versus Solution Focused Brief Therapy (SFBT)

1. Guided CBT Self-help
Parents will be given a self-help book to work through and parents will have 4 face-to-face sessions with a therapist and 4 telephone sessions over an 8 week period, with a total of 5 hours of therapist contact.
2. Solution Focused Brief Therapy (SFBT) involving an initial and a final face-to-face session with

the parents and child and 4 sessions in between with the child, totalling 5 hours of therapist contact. Both groups will be reassessed after the completion of treatment and at 6 months post-treatment.

Intervention Type
Behavioural

Primary outcome measure
The primary indicator of recovery is that the child's difficulties with anxiety are 'much' or 'very much' improved on the basis of clinical global impression as assessed post-treatment by an independent assessor, blind to treatment group and trained to a high level of reliability in the use of the measure.

Secondary outcome measures
Anxiety severity is assessed using the ADIS with parent and child and self-report questionnaires of anxiety symptoms, and the impact of anxiety on the child's life.
The outcome measure for cost-effectiveness will be the improvement status (much/very much improved), as well as a measure of 'days off school avoided' and generic quality of life as assessed by the child friendly EuroQol EQ-5D and CHU9D-c/p.

Overall study start date
01/02/2012

Completion date
31/01/2015

Eligibility

Key inclusion criteria
Children aged 5-12 years meeting standard PCAMHS criteria and with anxiety associated with clinical impairment as the primary presenting problem.

Participant type(s)
Patient

Age group
Child

Lower age limit
5 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
Planned Sample Size: 136; UK Sample Size: 136

Key exclusion criteria
1. Current prescription of psychotropic medication, or if psychotropic medication is prescribed, it should have been at a stable dose for at least 8 weeks prior to the study with agreement to maintain that dose throughout the study. If it is considered that a medication change is needed in the interests of the child, this child will no longer be eligible but will still be able to receive the usual treatment from PCAMHS.
2. The child or parent has a poor understanding of the English language.
3. The child or parent has a known physical or intellectual impairment (including autistic spectrum disorder).

Date of first enrolment
23/03/2012

Date of final enrolment
31/03/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Reading
Reading
United Kingdom
RG6 6AL

Sponsor information

Organisation
University of Reading (UK)

Sponsor details
Whiteknights
PO Box 217
Berkshire
Reading
England
United Kingdom
RG6 6AH

Sponsor type
University/education

Website
http://www.reading.ac.uk/

ROR
https://ror.org/05v62cm79

Funder(s)

Funder type
Government

Funder Name
NIHR Research for Patient Benefit Programme (UK) ref: PB-PG-0110-21190

Results and Publications

Publication and dissemination plan
The results will be published on 17/05/2017.

Intention to publish date
17/05/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in the University of Reading data repository.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2017		Yes	No