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Promoting tolerance of childrens feelings

Submission date	Recruitment status	[ ] Prospectively registered
22/03/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/03/2012	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/03/2018	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11832

Study information

Scientific Title
Promoting tolerance of childrens feelings: a randomised controlled trial

Study objectives
In a randomised controlled trial of childhood anxiety in the presence of a current parental anxiety disorder, the principal research questions are the following:

Phase 1
1. In comparison to parents who receive a control intervention, parents who receive an intensive tolerance of childrens negative emotion (TCNE) intervention will:
1.1. Report lower anxiety when taking part in a stressful task with their child
1.2. Exhibit lower levels of expressed anxiety and negativity
1.3. Display lower levels of physiological arousal, when engaged in mildly stressful task with their child.
2. In comparison to children in the control condition, children of parents who receive the tolerance of childrens negative emotion (TCNE) intervention will:
2.1. Report lower levels of anxiety
2.2. Exhibit lower levels of expressed anxiety
2.3. Have reduced physiological (heart rate) arousal whilst completing a stressful task with their parent.

Phase 2
1. In comparison to children in the control condition, children of parents who receive the tolerance of childrens negative emotion (TCNE) intervention as an adjunct to standard clinic treatment will demonstrate improved treatment outcomes in terms of overall improvement, recovery from anxiety diagnosis, and reduction in anxiety symptoms.

2. Childrens treatment outcomes will be mediated by change in parental tolerance of childrens negative emotions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
ref: 12/SC/0022

Study design
Randomised interventional treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
Anxiety

Interventions
Guided cognitive behavioral therapy (CBT) self-help delivered via parents (four sessions, 3 face to face, 1 telephone) with adjunctive Tolerance for Childrens Negative Emotions therapy (four sessions, 3 face to face, one telephone)
OR
Eight sessions of Guided Cognitive Behaviour Therapy (CBT) self-help (6 face to face, 2 telephone) followed up after 4 months

Intervention Type
Behavioural

Primary outcome measure
Primary indicator of recovery measured post treatment

Secondary outcome measures
Change in parental interactive behaviours measured at the end of study

Overall study start date
01/03/2012

Completion date
31/05/2013

Eligibility

Key inclusion criteria
The trial is open to children with a current primary diagnosis of a major anxiety disorder whose parent (i.e. primary carer) also currently experiences high anxiety.

Child:
1. Aged 7 to 12 years;
2. Primary diagnosis of DSM-IV generalised anxiety disorder, social phobia, separation anxiety disorder, panic disorder/agoraphobia, or specific phobia (must be at least one current comorbid anxiety disorder).

Parent:
1. Primary carer
2. Cohabitates with child
3. Currently experiences high anxiety on basis of
3.1. Scoring above clinical cut-offs on the DASS-A
3.2. Meeting diagnostic criteria for a current major anxiety disorder
4. Male and female participants

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
Planned Sample Size: 65; UK Sample Size: 65

Key exclusion criteria
Child:
1. Significant physical or intellectual impairment (including autistic spectrum disorders) that would impede treatment delivery
2. Current prescription of psychotropic medication (or, if psychotropic medication is prescribed, it should have been at a stable dose for at least 8 weeks with agreement to maintain that dose throughout the study)

Parent:
1. Significant intellectual impairment
2. Severe comorbid disorder that requires intervention outside of BCAC (e.g. severe major depressive disorder, psychosis, substance/alcohol dependence).

Date of first enrolment
01/03/2012

Date of final enrolment
31/05/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Reading
Reading
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Sponsor information

Organisation
University of Reading (UK)

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Whiteknights
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Sponsor type
University/education

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

ROR
https://ror.org/05v62cm79

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

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	01/08/2016		Yes	No