

Promoting tolerance of childrens feelings

Submission date 22/03/2012	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 22/03/2012	Overall study status Completed	☐ Protocol
Last Edited 06/03/2018	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☒ 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
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

Study type(s)

Treatment

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(s)

Primary indicator of recovery measured post treatment

Key secondary outcome(s)

Change in parental interactive behaviours measured at the end of study

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

7 years

Upper age limit

12 years

Sex

All

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

United Kingdom

England

Study participating centre

University of Reading

Reading

United Kingdom

RG6 6AL

Sponsor information

Organisation

University of Reading (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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	01/08/2016		Yes	No