

# Cognitive therapy for generalised anxiety in youth

<b>Submission date</b> 30/06/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/06/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/06/2019	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
8202

# Study information

## Scientific Title

Cognitive therapy for generalised anxiety disorder in children and young people: a pilot randomised controlled trial and qualitative investigation of their experience of treatment

## Study objectives

The main aim of this project is to evaluate the effect on symptoms and quality of life of a form of cognitive therapy targeting maintaining factors specific to generalised anxiety disorder (GAD) in children and adolescents. Outcomes for this 10-week, individual, child-focused treatment will be compared to outcomes for participants offered 10 weeks of psychoeducation and self-monitoring of symptoms (delayed treatment). Participants will be randomised to the two conditions. The main hypothesis is that cognitive therapy will be superior to the control intervention in reduction of GAD diagnostic status (primary outcome variable), and self-reported worry frequency, and quality of life. The secondary aims are to evaluate the children's subjective experience of the treatment and changes in cognitions that help to maintain worry.

On 04/02/2014 the anticipated end date was changed from 31/12/2010 to 30/11/2013. Publication of trial findings is expected in 2014.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

1. Royal Free Hospital and Medical School Research Ethics Committee approved on the 3rd December 2009 (ref: 09/H0720/127)
2. KCL/SLaM Research and Development approved on the 12th February 2010 (ref: R&D2010/015)

## Study design

Single centre randomised interventional treatment trial

## 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 below to request a patient information sheet

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

Topic: Mental Health Research Network; Subtopic: Anxiety; Disease: Anxiety

## **Interventions**

Intervention: cognitive therapy for GAD as developed by Dugas and Robichaud but adapted for use with pre-pubertal children and adolescents. Treatment will be weekly, individual and child-focused.

Control: single face-to-face session with a therapist wherein the child and the family will be provided with psychoeducation about anxiety and its treatment, symptom monitoring forms, and a date for the first treatment session in 10 weeks time.

Study entry: single randomisation only

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

GAD diagnostic status, measured with DSM-IV at entry to the trial (pre-treatment), post-treatment (10 weeks) or post-wait/self-monitoring

## **Secondary outcome measures**

1. Worry frequency, measured with Penn State Worry Questionnaire for Children (PSWQ-C)
2. Quality of life as measured by the Paediatric Quality of Life Enjoyment and Satisfaction Questionnaire

Measured at baseline, mid-treatment (5 weeks), end of treatment (10 weeks) and at 3-month follow up assessment.

## **Overall study start date**

01/01/2009

## **Completion date**

30/11/2013

# **Eligibility**

## **Key inclusion criteria**

1. Children/young people aged 10 - 18 years, either sex
2. Diagnosis of GAD according to Diagnostic and Statistical Manual of Mental Disorders, version 4 (DSM-IV) criteria
3. Consecutively referred to a National and Specialist children's anxiety clinic (if they give informed consent)
4. Participants with a comorbid Axis 1 diagnosis will be included provided GAD is the primary disorder in need of treatment

## **Participant type(s)**

Patient

## **Age group**

Child

**Lower age limit**

10 Years

**Upper age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned sample size: 40; UK sample size: 40

**Total final enrolment**

40

**Key exclusion criteria**

1. Psychosis or learning difficulties (estimated intelligence quotient [IQ] below 70) or autistic spectrum disorder
2. Another mental health problem other than GAD that is more in need of treatment at the time of referral (such as severe depression)

**Date of first enrolment**

01/01/2009

**Date of final enrolment**

30/11/2013

## **Locations**

**Countries of recruitment**

Sweden

United Kingdom

**Study participating centre**

**Lund University**

Lund

Sweden

221 00

## **Sponsor information**

**Organisation**

King's College London (KCL) (UK)

**Sponsor details**

Strand  
London  
England  
United Kingdom  
WC2R 2LS

**Sponsor type**

University/education

**Website**

<http://www.kcl.ac.uk/>

**ROR**

<https://ror.org/0220mzb33>

## Funder(s)

**Funder type**

Government

**Funder Name**

Research for Patient Benefit Programme (ref: PB-PG-0808-17094)

**Alternative Name(s)**

NIHR Research for Patient Benefit Programme, RfPB

**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?
<a href="#">Results article</a>	results	01/12/2019	04/06/2019	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No