

Cognitive therapy for generalised anxiety in youth

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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

10 years

Upper age limit

18 years

Sex

All

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

United Kingdom

Sweden

Study participating centre

Lund University

Lund

Sweden

221 00

Sponsor information

Organisation

King's College London (KCL) (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, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2019	04/06/2019	Yes	No
HRA research summary			28/06/2023	No	No