ISRCTN50951795 https://doi.org/10.1186/ISRCTN50951795

Cognitive therapy for generalised anxiety in youth

Submission date	Recruitment status	[ ] Prospectively registered
30/06/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/06/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/06/2019	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
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 tageting 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?
Results article	results	01/12/2019	04/06/2019	Yes	No
HRA research summary			28/06/2023	No	No