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# Coping with unusual experiences for children study

**Submission date**
26/01/2013

**Recruitment status**
No longer recruiting

**Registration date**
04/04/2013

**Overall study status**
Completed

**Last Edited**
18/01/2019

**Condition category**
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

## Plain English summary of protocol

Background and study aims
The Coping with Unusual Experiences for Children Study (CUES) is an evaluation of Cognitive Behavioural Therapy (CBT) for children and young people aged 8-14 years, presenting to Child and Adolescent Mental Health Services (CAMHS) with unusual experiences and emotional distress. Unusual experiences include things like hearing voices that other people cannot hear, seeing, feeling or smelling things that other people cannot, or finding that things look somehow odd or different. These experiences are much more common than most people think and often do not cause any problems for the people experiencing them. They might even be enjoyable. However, sometimes these experiences can be upsetting or worrying to the person who has them, or can stop the person doing what they normally do. This in turn can interfere with school or work, friendships and family relationships. The CUES study is designed to find out whether a specially designed CBT package reduced distress for these young people. We know from previous studies that young people do not always talk about unusual experiences unless they are asked directly. We are therefore inviting the families of all young people referred to our local community CAMHS services to participate in the study. In the first part of the study, everybody who consents will complete a series of questionnaires about how they are feeling, how they think about things and their life experiences. Young people reporting unusual experiences and distress are then invited to take part in the second part of the study, which is the CBT evaluation. We will compare the young people taking part in the CBT straight away, with the young people taking part after a three month wait (the waitlist control group). We predict that participants will find the intervention acceptable and will show improvements in emotional distress, compared to the waitlist control group. We also predict that they will show a reduction in the severity of their unusual experiences, and improvements in general wellbeing and day to day functioning.

Who can participate?
All young people referred to community services in the CAMHS Clinical Academic Group of the South London & Maudsley NHS Foundation Trust (UK) can take part, providing their parents consent. Families whose understanding of spoken and written English is insufficient to participate without an interpreter will not be excluded, providing the clinical service is able to provide an interpreter.

What does the study involve?
For young people and their parents or caregivers, taking part in the study will involve completing questionnaires measuring how they think and feel, how they react to particular situations, and their life experiences. Young people who report unusual experiences and distress will be offered the CBT package straight away, or after a three month wait. Who joins in straightaway and who has to wait will be decided randomly, by a process a bit like tossing a coin. The CBT is delivered by a trained therapist, either straight away or after a three month wait. The young people and their parents in this part of the study will complete the questionnaires again at 3 months, and one month after the end of therapy. Therapy usually lasts for 12 weeks, with approximately weekly sessions. Sessions are arranged at time to suit the young person and their family, and we can meet in schools or other community venues if this is more convenient for them.

We will use the questionnaires to measure change in emotional distress for young people from the start of their involvement with the study (week 0) to after the first twelve weeks (week 12). We will also measure this one month after the end of therapy, to see whether any changes are lasting. We will compare young people receiving the CBT intervention with young people waiting for the intervention.

What are the possible benefits and risks of participating?
We hope that the CBT intervention will be helpful, and do not expect there to be any particular risks associated with taking part.

Where is the study run from?
The study is taking place in the CAMHS Clinical Academic Group in the South London and Maudsley NHS Foundation Trust (UK), which is part of the Academic Health Sciences Centre, King s Health Partners.

When is the study starting and how long is it expected to run for?
The study has been recruiting participants since May 2011, and aim to finish in March 2014. We aim to complete baseline assessments with 90 young people and to deliver CBT to 60 young people.

Who is funding the study?
Guys and St Thomas Charity (UK)

Who is the main contact?
Dr Suzanne Jolley
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# Contact information

### Type(s)
Scientific

### Contact name
Dr Suzanne Jolley

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
V1 13th January, 2010

# Study information

### Scientific Title
Coping with unusual experiences and emotional problems: an evaluation of a training package for children aged 8-14 years

### Acronym
CUES

### Study objectives
Primary hypothesis:
Children receiving the intervention immediately will show a clinically significant reduction in emotional symptoms by the end of treatment compared to those on the waiting list.

Secondary hypotheses:
1. Children receiving the intervention immediately will show a clinically significant improvement in occurrence of unusual experiences and associated distress, in general wellbeing, anxiety, and in functioning.
2. Improvements following the intervention will be maintained at follow-up.

Additional investigations:
1. The prevalence of unusual experiences in children in Tier 2 CAMHS services will be determined by a small audit
2. The cognitive, social, affective and functional characteristics of children in these services with and without unusual experiences and distress will be described.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)

London Hampstead Research Ethics Committee, 28/4/2011, ref: 11/LO/0023

## Study design
Randomised controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Other

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please contact suzanne.jolley@kcl.ac.uk to request a patient information sheet

## Health condition(s) or problem(s) studied
Mental health, Child and Adolescent

## Interventions
Comparing a CBT intervention to waitlist control for children with unusual experiences and emotional distress.

Cognitive behavioural therapy: 9-12 sessions lasting 40-50 minutes, delivered over 2-3 months. Sessions covers engagement, assessment, goal-setting, socialisation to a CBT model, coping strategies, problem solving, understanding unusual experiences and cognitive biases, behavioural experiments, troubleshooting, review and ending.

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome measure
Emotional symptoms score on the Strength & Difficulties Questionnnaire (SDQ, child reported), measured at baseline and at 3 months.

## Secondary outcome measures
1. Frequency of unusual experiences
2. Associated distress and impact on the childs life (child reported; using a modified version of the PLE)
3. General well being, anxiety, mood and functioning

All measures (primary and secondary) will be repeated one month following the end of the intervention.

### Overall study start date
01/07/2011

### Completion date
31/12/2013

## Eligibility

### Key inclusion criteria
1. Aged 8-14 referred to Child and Adolescent Mental Health Services (CAMHS) Tier 2 services
2. Scoring in the clinical range on the emotional symptoms subscale of the SDQ
3. Reporting ≥ one psychotic-like" experiences (PLE)
4. Adequate English to complete the measures
5. Planning to reside locally for the duration of the study (in order to complete therapy and measures)

### Participant type(s)
Patient

### Age group
Child

### Lower age limit
8 Years

### Upper age limit
14 Years

### Sex
Both

### Target number of participants
60

### Key exclusion criteria
1. Aged <8 or >14 years at the time of referral
2. Non-clinical SDQ emotional symptoms score
3. No PLEs
4. Insufficient command of English to complete the measures; unstable residential arrangements (making a move away likely)

### Date of first enrolment
01/07/2011

### Date of final enrolment
31/12/2013

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**King's College London**
London
United Kingdom
SE5 8AF

## Sponsor information

### Organisation
King's College London (UK)

### Sponsor details
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### Sponsor type
Hospital/treatment centre

### Website
http://www.kcl.ac.uk/iop/research/office/about/index.aspx

### ROR
https://ror.org/0220mzb33

## Funder(s)

### Funder type
Charity

### Funder Name
Guy's and St Thomas' Charity ref: R100417

### Alternative Name(s)
Guy's and St Thomas' Charity, Guy's and St Thomas' Foundation, GSTTFoundation

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Trusts, charities, foundations (both public and private)

### 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 | 01/09/2018 | 18/01/2018 | Yes | No |