

Coping with unusual experiences for children study

Submission date 26/01/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/04/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/01/2019	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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

Contact details

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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)

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 Questionnaire (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 child's 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 \geq 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