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Coping with Unusual ExperienceS for 12-18 (CUES+)

Submission date	Recruitment status	[X] Prospectively registered
08/01/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/01/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/12/2020	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Plain English Summary

Background and aims: Childhood 'unusual experiences' (such as hearing voices that others cannot, or suspicions of being followed) are common, but can become more distressing during adolescence, especially for young people in contact with Child and Adolescent Mental Health Services (CAMHS). Unusual experiences associated with distress (UEDs) occur in psychosis, a rare but serious mental health condition. UEDs also occur in other common adolescent mental health problems, and make it less likely that young people will recover well. Research in adults has shown that the talking treatment cognitive behavioural therapy for psychosis (CBTp), is helpful, and saves money by reducing hospital admissions. National guidance recommends that young people with psychosis or UEDs receive CBTp, to help them feel less distressed, which may also improve their future mental health. More research in children is needed, to make sure that the recommendations suit them as well as adults. CAMHS therapists need specialist training and supervision to deliver CBTp. Services need to ask about UEDs consistently, as children may not otherwise report them. Our study aims to find out whether CBTp is helpful and cost-effective for adolescents with UEDs. We will support therapists in the service to deliver CBTp.

Who can participate:
The study is open to all users of adolescent community mental health services who report a UED. The ages covered by the service at entry are from the 12th birthday up to, but not including the 18th birthday. The age range of participants will therefore be 12-18 years.

What does the study involve?
Adolescents in CAMHS are invited to complete questionnaires about UEDs and how they are feeling. Those that have UEDs are then randomly allocated into one of two groups. Those in group 1 are offered CBTp straight away. Those in group 2 are offered it after 6 months. Participants complete questionnaires about their mood, experiences, and thinking style at the start of the study. This is repeated after 4 months, when the CBTp is finished, and again after 6 months, to see if any helpful changes are lasting. We compare the group starting CBTp straight away with the 6-month-wait group on measures of distress, UEDs and health and social costs. The CBTp lasts for up to 16 sessions and focuses on understanding and managing UEDs,

emotional difficulties and social problems. We also invite families to up to four family support meetings and ask parents to complete measures of their own wellbeing and their child's difficulties.

What are the possible benefits and risks of taking part?
The primary benefit will be to young people with UEDs and their families, who will have access to specialist psychological interventions. The local services will benefit from the training of front line staff in the delivery of high quality psychological work and local stakeholders will benefit from improved access and greater clarity regarding care pathways for young people with UEDs. We do not expect there to be particular risks of taking part, but if any participant finds any part of the study upsetting in anyway, an experienced clinician connected with the study can offer support.

Where is the study based?
In the community Child and Adolescent Mental Health Services (CAMHS) of the South London and Maudsley NHS Foundation Trust, working in collaboration with King's College, London.

When is the study starting and how long is it expected to run for?
October 2014 to September 2017.

Who is funding the study?
The National Institute for Health Research (UK)

Who is the main contact?
Dr. Suzanne Jolley

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17963

Study information

Scientific Title
Coping with Unusual ExperienceS for 12-18 year olds (CUES+): A transdiagnostic randomised controlled trial of the effectiveness of cognitive therapy in reducing distress associated with unusual experiences in adolescent mental health services

Acronym
CUES+

Study objectives
1. Clinical outcomes for young people with UEDs will be improved by the addition of cognitive behaviour therapy for psychosis (CBTp) to routine care
2. Effect sizes will be comparable to, or larger than, those found in the adult literature
3. The intervention will be cost-effective

Ethics approval required
Old ethics approval format

Ethics approval(s)
London Hampstead NRES Committee, ref: 14/LO/1970

Study design
A single-centre trial of a cognitive therapy intervention compared to waitlist control

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

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
Distressing unusual experiences (UEDs) in adolescents presenting to community Child and Adolescent Mental Health Services (CAMHS).

Interventions

Therapy will comprise up to 16 sessions, delivered over 16 weeks, including individual CBTp adapted for adolescents and 3-4 family support sessions. This is crucial when working with young people and has been requested by parents consulting on our studies. Family work comprises recognition and understanding of the child's difficulties, sharing the intervention plan, and troubleshooting any key family difficulties. Individual work focuses on developing a collaborative understanding of UEDs, together with skills in affect regulation, managing negative automatic thoughts, behavioural tests, dealing with social difficulties and adverse life events, recognising and compensating for cognitive biases and a section on taking the work forward and preventing future difficulties. Therapy is tailored to take account of the developmental stage and presenting issues of the child/young person with an emphasis on identity formation, understanding self in relation to the experience of psychosis/UEDs, social inclusion and self esteem. Therapy materials have been designed to be fun, interactive and engaging.

Intervention Type
Behavioural

Primary outcome measure
Distress at 16 weeks, assessed using the Emotional Problems subscale of the child reported version of the Strengths and Difficulties Questionnaire (SDQ). The SDQ is well-validated and routinely used in local services for youth up to 19 years.

Secondary outcome measures
Child-reported UED severity at 16 weeks, adverse events including A&E attendance and incidents of self harm, and economic costs, including QALYs. We will also measure the cognitive, social, emotional and behavioural therapy targets hypothesised to maintain UEDs, and sessional measures of therapy progress.

Overall study start date
05/01/2015

Completion date
30/09/2017

Eligibility

Key inclusion criteria
1. Presenting to local CAMHS
2. Current UED
3. Aged 12-18 years
4. Available for the study duration
5. Sufficient English language ability to be able to complete assessment measures and therapy (with interpreter support if necessary)

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 120; UK Sample Size: 120; Description: 120 participants with UEDs; 60 will be allocated to the immediate treatment group and 60 to the waiting list control group.

Key exclusion criteria
1. Learning disability (IQ<70)
2. UED secondary to known neurological condition (e.g. epilepsy or brain injury) or limited to states of acute intoxication/withdrawal in the context of substance misuse

Date of first enrolment
13/01/2015

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College
London Institute of Psychiatry
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
King's College London

Sponsor details

Room 1.8
Hodgkin Building
Guy's Campus
London
England
United Kingdom
SE1 4UL

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
We will aim to submit a trial outcomes paper for publication within a year of completion. Baseline studies of sample characteristics and psychosocial correlates of unusual experiences will be submitted during the final year of the trial.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	04/12/2017	17/12/2020	Yes	No
HRA research summary			28/06/2023	No	No