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DECRYPT: Delivery of cognitive therapy for young people after trauma

Submission date	Recruitment status	[X] Prospectively registered
24/10/2016	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/10/2016	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
20/12/2024	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Post-traumatic stress disorder (PTSD) is a type of anxiety disorder that is triggered by a stressful or traumatic event. The symptoms of PTSD can be extremely disabling, and may include flashbacks, nightmares, avoidance of anything that may remind a person of the trauma, and hyperarousal (heightened anxiety that can cause anger outbursts, problems concentrating or sleeping). PTSD in young people often occurs with other mental health conditions, greatly impacts on educational, social and daily functioning, and may last for years or even decades. The Royal College of Psychiatrists estimates the prevalence of PTSD in UK youth to be 3%. Studies have shown that multiple traumatic experiences, such as physical or sexual abuse, are not rare (4-6% of children and adolescents in England) and those affected often go on to develop PTSD. Cognitive Therapy for PTSD (CT-PTSD) is a type of talking therapy which works by changing the way people think and behave to alleviate PTSD symptoms. It has been shown to be effective at treating adults but it is not known whether it would be an effective treatment for children and adolescents with PTSD. The aim of this study is to investigate the effectiveness of CT-PTSD in the treatment of PTSD in children and adolescents who have experienced multiple traumatic experiences.

Who can participate?
Children and adolescents aged between 8 and 17 who are experiencing PTSD after multiple traumatic experiences.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive up to 15 sessions of CT-PTSD over a period of five months. The sessions last for around 60-90 minutes and are run by trained NHS child and adolescent or youth mental health service clinicians. Those in the second group receive usual treatment for the duration of the study. At the start of the study and then after 5 months, participants complete questionnaires to find out whether their PTSD symptoms have improved.

What are the possible benefits and risks of participating?
Participants who receive CT-PTSD may benefit from improvement in their PTSD symptoms, however this is not yet known. There is no evidence from previous studies of youth or adults

receiving this type of treatment that participants will experience any negative side effects. Any distress experienced during therapy is short-lived and outweighed by the benefit of receiving treatment.

Where is the study run from?
University of East Anglia (UK)

When is the study starting and how long is it expected to run for?
March 2016 to December 2020

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

Who is the main contact?
Dr Richard Meiser-Stedman
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Study website
http://www.uea.ac.uk/decrypt/home

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
188916

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
31869

Study information

Scientific Title
Cognitive Therapy for the treatment of post-traumatic stress disorder (PTSD) in youth exposed to multiple traumatic stressors: a phase II randomised controlled trial

Acronym
DECRYPT

Study objectives
Cognitive-Therapy for PTSD (CT-PTSD) will be superior to treatment as usual (TAU) five months post-randomisation with respect to symptoms of post-traumatic stress disorder (PTSD) in 8-17 year olds who have experienced multiple traumas and who are receiving care from NHS child and adolescent mental health services or other NHS youth services.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/07/2016, East of England - Cambridge South Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; 0207 104 8208; cambridgesouth.rec@hra.nhs.uk), ref: 16/EE/0233

Study design
Randomised; Interventional; Design type: Treatment, Screening, Diagnosis, Psychological & Behavioural

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 use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Post-traumatic stress disorder

Interventions
A remote randomisation service will assign allocation to groups coordinated by the Norwich Clinical Trials Unit. Allocation is by pre-set lists of permuted blocks with randomly distributed block sizes (agreed with the trial statistician). The trial allocation ratio is 1:1. Randomisation will be stratified by: initial PTSD symptom severity (CRIES-8 score <29 vs ≥29); and site (i.e. NHS Trust from where the participant was recruited).

Intervention group: Participants receive treatment with CT-PTSD (Cognitive therapy-PTSD). This involves participating in up to 15 treatment sessions (typically 10-12, of 60-90 minutes duration), to be completed within five months of randomisation where possible. The sessions themselves focus on psychoeducation, exposure (to help desensitise patients to trauma memories), cognitive elements (to reframe the meanings and interpretations associated with trauma and its aftermath), and coping management (e.g. problem-solving, anxiety management). The CT-PTSD will be delivered by NHS child and adolescent or youth mental health service clinicians who have completed intensive training in CT-PTSD by a member of the trial team. CT-PTSD will be delivered wherever is permitted and feasible for local clinicians (e.g. in NHS mental health clinics, local GP surgeries, home). Following the completion of a course of CT-PTSD, usual NHS care arrangements will apply for participants in this arm, coordinated by the trial team, the participants' GPs and the original referrers.

Control group. Participants receive treatment as usual for the duration of the study. Mental health professionals and others involved in the care of the participants in the TAU arm will be encouraged to provide whatever help they deem necessary, e.g. general clinical management, supportive counselling, family therapy, medication. Therapist contact in the TAU arm would not be prescribed by trial participation in any way, with one exception: the participants will receive no contact with the trained Trial Therapists delivering CT-PTSD.

PTSD severity (as indexed by the routine outcome monitoring questionnaire for PTSD, the CRIES-8) at post-treatment (i.e. five months post-randomisation) is the primary clinical outcome. A mid-treatment phase assessment will be undertaken at 2.5 months post-randomisation to measure mediation mechanisms. A follow up assessment will be conducted six months after the end of treatment (i.e. 11 months post-randomisation); a 24 month follow up assessment (i.e. 29 months post-randomisation) will be completed if resources are available to do so.

Intervention Type
Other

Phase
Phase II

Primary outcome measure
Levels of symptoms of PTSD are measured using the Child Revised Impact of Event Scale (CRIES-8) completed at baseline and at 2.5, 5 and 11 months post-randomisation.

Secondary outcome measures
1. PTSD severity is measured using the Children's PTSD Symptom Scale for DSM-5, interviewer version (CPSS-I-5), at baseline, 5 and 11 months
2. Self-reported PTSD severity is measured using the Child and Adolescent Trauma Screen (CATS), with additional items addressing dissociation and complex PTSD symptoms at baseline, 2.5, 5 and 11 months.
3. Anxiety and depression are is measured using the Revised Child Anxiety and Depression Scale

(RCADS) at baseline, 5 and 11 months
4. Suicidal ideation is measured using selected items from the Mood and Feelings Questionnaire (MFQ) at baseline,5 and 11 months
5. Irritability is measured using the Affective Reactivity Index (ARI; child and parent-report versions) at baseline, 5 and 11 months
6. Child's overall severity and functioning is measured using the Children's Global Assessment Scale at baseline, 5 and 11 months
7. Parent reported mental health and well-being measured using the Strengths and Difficulties Questionnaire at baseline, 5 and 11 months
8. Personality traits are measured using the McLean Screening Instrument (caregiver version) at baseline, 5 and 11 months
9. Quality of life is measured using the Youth version of EuroQol EQ-5D (EQ-5D-Y) at baseline, 5 and 11 months

Health economic outcomes:
1. Resource use is measured using the Child and Adolescent Service Use Schedule (CA-SUS) at baseline, 5 and 11 months
2. Views of the young people, their families and clinicians will be captured using qualitative interviews when therapy has been concluded (for participants and family members) or after the trial data collection has concluded (for service managers and commissioners).
3. Cost-effectiveness of CT-PTSD will be assessed using CA-SUS and EQ-5DY (as above) and additional data will be collected directly from clinicians and service records regarding CT-PTSD and TAU contact time and indirect time.

If resources allow, an additional 29 month follow up assessment will take place, where the CRIES-8, CPSS-I-5, CATS, RCADS, CGAS and SDQ will be re-administered.

Overall study start date
01/03/2016

Completion date
30/06/2024

Eligibility

Key inclusion criteria
1. Children and adolescents aged 8-17 years
2. Experiencing high levels of PTSD symptoms (scoring 17 or above on the CRIES-8)
3. Diagnosis of PTSD (as defined by DSM-5) following multiple trauma exposure

Participant type(s)
Patient

Age group
Mixed

Lower age limit
8 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
Planned Sample Size: 120; UK Sample Size: 120

Total final enrolment
120

Key exclusion criteria
1. Any change of prescribed psychiatric medication within the past two months
2. PTSD symptoms only related to a single traumatic event
3. Developmental/neurodevelopmental disorder (e.g. autism)
4. Diagnosis of intellectual disability
5. Primary psychiatric diagnosis that warrants treatment ahead of PTSD (e.g. psychosis, severe depression, suicidal behaviour)
6. Inability to speak and understand English
7. On-going threat (e.g. living with an abuser) or safeguarding issue
8. Strong likelihood of being unable to complete treatment (e.g. imminent house move or placement move)
or
9. History of organic brain damage

Date of first enrolment
01/12/2016

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
University of East Anglia
Norwich Research Park
Norwich
United Kingdom
NR4 7TJ

Sponsor information

Organisation
University of East Anglia

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Sponsor type
University/education

ROR
https://ror.org/026k5mg93

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

The results of the trial will be disseminated, regardless of the direction of effect, with the primary output being a planned publication in a peer-reviewed journal. Ownership of the data arising from the study resides with the trial team. The publication policy will be in line with rules of the International Committee of Medical Journal Editors. The TMG will decide on authorship with any difficulties being resolved by the TSC.

Intention to publish date

30/06/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		01/07/2021	05/07/2021	Yes	No
HRA research summary			28/06/2023	No	No