

# DECRYPT: Delivery of cognitive therapy for young people after trauma

<b>Submission date</b> 24/10/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 24/10/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/09/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## 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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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Integrated Research Application System (IRAS)**  
188916

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
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

## Study type(s)

Treatment

## 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(s)**

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.

## **Key secondary outcome(s)**

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 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.

**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

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

8 years

**Upper age limit**

17 years

**Sex**

All

**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**

United Kingdom

England

Wales

**Study participating centre**

**University of East Anglia**

Norwich Research Park

Norwich

United Kingdom

NR4 7TJ

## **Sponsor information**

**Organisation**

University of East Anglia

**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

**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?
<a href="#">Results article</a>		15/09/2025	25/09/2025	Yes	No
<a href="#">Protocol article</a>		01/07/2021	05/07/2021	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes