ISRCTN38238325 https://doi.org/10.1186/ISRCTN38238325

Supporting services to deliver trauma-focused cognitive-behavioural therapy for care-experienced young people: a pilot implementation study

Submission date
20/09/2022

Recruitment status
No longer recruiting

Registration date
07/10/2022

Overall study status
Completed

Last Edited
26/09/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Young people in care cannot live with their family, because it is too unsafe. They might not have had enough food to eat or a safe space to sleep. Some might have been abused or seen lots of violence.

Many of these children are struggling with mental health difficulties. One such difficulty is posttraumatic stress disorder (PTSD). PTSD can develop after someone has been through trauma, like abuse or other situations where they felt very scared for their life or someone else's life. People with PTSD experience symptoms that include "flashbacks", which are memories of their trauma that make them feel like they are in danger again. They might also have thoughts like, "I can't trust anyone" or "nowhere is safe". They might have trouble sleeping or listening in class. If they don't get help with these symptoms they can become worse and make lots of things very difficult – like making friends and doing well in school.

We have very good treatments available that research shows can help children to recover from these problems, called trauma-focused cognitive behaviour therapies. But we know that many children with care experience, who have PTSD, won't get this treatment. Our project is about saying that young people with care experience deserve our best evidence-based treatments. Treatments that have been researched and are the best way for children to be supported to overcome their mental health difficulty, like PTSD. We will work with services that give mental health treatments to children in care, and help them to look at whether their children have PTSD, and if they do, give them the best-evidenced treatment.

This project will help us understand why services might or might not use evidence-based treatments and how this can be changed, to help the mental health of these young people.

Who can participate?

The main participants in this study are mental health services and mental health workers who work with care-experienced young people. These are clinicians and therapists from any professional background, who currently regularly provide mental health interventions to care-experienced young people. Most services are CAMHS or targeted CAMHS (specific services for

children in care), but some are also social-care-based mental health services.
For the embedded pilot effectiveness trial participants are young people who are: (1) a care-experienced young person – our study is focused on three specific groups, namely those under the care of a local authority, adopted from care, or on a special guardianship order; (2) aged 8yrs – 17yrs 11mo; (3) attending a participating mental health service and been offered tf-CBT; (4) have adequate English skills and intellectual capacity to complete questionnaires (based on clinician and caregiver judgment).

What does the study involve?
For service providers: they will be asked to attend a training on cognitive therapy for PTSD (a type of trauma-focused CBT), agreed with their service. Before this training, therapists will be asked to complete a brief online questionnaire with some basic information about their professional background and experience and their thoughts on different clinical decisions (not to be shared with their colleagues or service). Following training, every 3 months they will be invited to attend a virtual focus group about their experiences using the PTSD screening tool and treatment, as well as challenges and how they might have overcome obstacles. If unable to attend these sessions or if preferred, therapists will be invited to a 1:1 phone call or survey. The study runs for approximately 12-18 months, so therapists will be invited to 4-6 interviews in that time. Prior to these focus groups/interviews, they will also be sent a brief descriptive questionnaire, to collect information on the individual level about whether or not they have used the screening tool or treatment, and also supervision access.
For young people: it involves doing some short questionnaires, which take about 15-20 minutes, asking about their thoughts and feelings at the moment. These can be done on a computer, on the phone, or at home. They will be asked to do these three times: soon after consenting to the study (before they start their tf-CBT treatment or early on in their treatment), about 2-4 months later when their treatment ends, and then again about 3 months after that. Some young people might also be invited to do a longer qualitative interview. Caregivers will also be invited to complete questionnaires about their views on the young person's mental health.

What are the possible benefits and risks of participating?
For service providers: the answers from this research will teach us how we can best support services and service providers to deliver NICE-recommended mental health treatments, like tf-CBTs. Participants' answers will also highlight the complexities and challenges services face, so will contribute to our ability to advocate for their needs and for our understanding of how we can provide best-evidenced support to care-experienced young people.
For young people: the answers from this research will teach us about how to better help other young people who have experiences of being in care, so we can learn about how we might give better support for mental health for young people in care.

Where is the study run from?
University College London (UK)

When is the study starting and how long is it expected to run for?
January 2022 to December 2023

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Dr. Rosie McGuire, rosie.mcguire@annafreud.org

Contact information

Type(s)
Scientific

Contact name
Dr Rosie McGuire

ORCID ID
https://orcid.org/0000-0003-1523-8225

Contact details
University College London
26 Bedford Way
London
United Kingdom
WC1H 0DS
+44 (0)20 7679 2000
rosie.mcguire@annafreud.org

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
307056

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 52819, IRAS 307056

Study information

Scientific Title
The ADaPT trial: Cross-sector implementation of trauma-focused CBT for children in care with posttraumatic stress disorder

Acronym
ADaPT

Study objectives
This is an exploratory implementation study, so there are no primary hypotheses. However, example predictions include that implementation success will be predicted by:
1. Higher numbers of practitioners who were CBT-trained prior to their tf-CBT training.
2. Higher endorsement in believe around using evidence-based treatments.
3. Access to supervision within service.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/06/2022, London -Hampstead Research Ethics Committee (Temple Quay House, 2 The Square, Bristol Research Ethics Committee Centre, BS1 6PN, UK; +44 2071048345; hampstead.rec@hra.nhs.uk), ref: 22/LO/0361

Study design
Interventional non-randomized

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Care-experienced young people (those in care, adopted, or on special guardianship order) experiencing high posttraumatic stress disorder symptoms

Interventions
Our study design has been developed with input from care-experienced young people, caregivers, and local authorities, as well as with input from Trust Research & Development teams.
Broadly, the methods fall into three categories:
(1) The service implementation (implementation research).
(2) Basic evidence of effectiveness, derived from anonymised service data.
(3) Evidence of effectiveness and mechanisms of change, from new data collection.
The project runs for 2 years and will actively recruit and consent participants for approximately 18 months of that time.
SERVICE IMPLEMENTATION (1) AND ANONYMISED SERVICE DATA (2):
This is an implementation research trial. The main focus of this trial is to learn how services can be best supported to routinely assess for PTSD and deliver trauma-focused cognitive behaviour therapy.
Participating services will primarily be CAMHS or specialist CAMHS, but can also include social-care-based mental health services and third-sector-based mental health services. Each participating service is seen as a 'case', to form a case series on implementation strategies.
Participating services will identify their staff who routinely provide mental health interventions to care-experienced young people. This will primarily be Looked-After young people, but may include those on special guardianship orders, or those adopted from care. These staff will be offered training in cognitive therapy for PTSD – a type of trauma-focused cognitive behaviour therapy. Some services may already be trained in a trauma-focused cognitive behaviour therapy. If this is the case, we will collaborate with the service to determine if further training would be provided. If no further training is required, they can still participate so we can learn how they came to be implementing this treatment.
The research team will then track the progress of the service, via a) the collation of routinely collected service data and b) via 3-monthly descriptive survey feedback and qualitative interviews/focus groups with the service providers and managers. Approximately every 3 months, the team will work with the Trusts and services to gather anonymised routinely collected service data that tracks their progress. This includes:

(a) how many care-experienced young people were assessed for PTSD, using a routine PTSD screener called the CRIES-8;
(b) what percentage of these scored above the clinical cut-off; (c) what percentage of these were offered a trauma-focused cognitive behavioural therapy.
We will also collect data on:
(a) the average number of sessions completed by young people who started the treatment;
(b) key recorded reason for treatment completion (e.g., did not attend, treatment finished, etc).
This will all be collected as anonymous service data. No identifiable information (e.g., names, addresses, local authority) will be collected. This is the ideal anonymised data we aim to collect, however, a key implementation question is how and if this type of data can be collated for care-experienced young people.
Approximately every 3-months, those who received the training and their service managers will be invited to complete a short descriptive questionnaire on whether they have used the CRIES-8 and tf-CBT and their supervision availability, as well as be invited to participate in 1:1 qualitative interviews or focus groups (depending on preference) to learn about what has and has not helped in terms of implementing the PTSD screening tool and providing the intervention. This can be done in person or virtually. Being mindful of service capacity, not every clinician /professional needs to attend every interview. It is up to them to decide whether they can fit it in, and each participant will provide informed consent prior to their participation. If they cannot attend the interview, they will also have the option of completing some open-ended questions online that map the qualitative interview questions, to ensure we are collecting as much information as possible on potential facilitators and barriers. Where barriers are identified, the research team will work with the service to identify potential solutions to trial within the individual service. These interviews and focus groups will be audio recorded and transcribed, then coded using framework analysis, an inherently comparative form of thematic analysis. No identifiable information will be collected in these interviews. Any information shared by clinicians that could be identifiable will be removed at the transcription stage. This iterative process across the whole project allows us to continually update the implementation framework. As part of the study aims to understand what constitutes best practice for implementation, in different regions, we will record the region the participant is based (e.g., North, East, South West England, London) and service/sector type.
The secondary aim of the project is to gather some basic feasibility and effectiveness data on the intervention. Specifically, we aim to establish the most feasible route to recruit care-experienced young people from these services into a trial and whether it is feasible to understand effectiveness within the context of an implementation trial (e.g., where fidelity is not a key focus and there is no comparison group). If possible, we also aim to understand the basic effectiveness of the intervention (i.e., symptom change and mechanisms of change), using a simple baseline – post-treatment and follow-up design. We will collect the information related to this aim via two methods: i) the collation of routinely collected anonymized service data and ii) the collection of new data from young people, to further explore the effectiveness and mechanisms of change.
Where possible, we will collate anonymised service data on two measures, which are part of the NHS Core Outcomes Measure battery (CORC): the child revised impact of events scale (CRIES-8 /16) – a brief screen of PTSD symptoms, and the revised anxiety and depression scale (RCADS) – a brief measure of anxiety and depression symptoms. Via the Trusts and services, this anonymised routinely collected service data will be provided to the research team. Part of the implementation project also explores the feasibility of collating this type of data on care-experienced young people and understanding implementation issues around services using these routine outcome measures. If the service ultimately decides to use a different CORC measure (for example, a different depression measure), we will collate this data instead of the RCADS. This means that we will collect whatever mental health measure the service uses to track mental health, although they will be encouraged to use the CRIES-8 and RCADS.

YOUNG PERSON INVOLVEMENT (3):
Eligible young people who were offered the treatment will be invited to participate in a feasibility and pilot effectiveness and mechanism project, which takes a baseline, post-treatment, 3-monthly design, and includes questionnaires and a qualitative interview. The young person's clinician or the clinical team will provide the young person and caregiver with a study flyer and will ask them whether they would be interested in hearing more about the project. If they agree to hear further information, the research team will contact them via the primary caregiver (e.g., adoptive parent, guardian, foster carer, key worker if in residential care). If more appropriate, the research team will contact the young person directly (e.g., if 16+ years old and they live in semi-independent living or residential care home). The young person and caregiver will then be provided with audience-appropriate information sheets and the study will also be explained verbally. If they would like to participate, they will then complete informed consent and assent procedures before completing the questionnaires and interview.

Quantitative questionnaires seek to explore the effectiveness of this treatment when used in routine practice with care-experienced young people. Questionnaires are all validated for use with this age group. The qualitative interview seeks to hear more about the young person's experiences of being assessed for PTSD and being offered the treatment (and doing the treatment, if relevant). Here we will use purposive sampling methods, to ensure we are recruiting a diverse and inclusive sample of care-experienced young people, including those who did and did not complete the treatment.

Intervention Type
Behavioural

Primary outcome(s)
The project is primarily interested in understanding barriers and facilitators of services conducting routine screening for PTSD and the delivery of tf-CBT (cognitive therapy for PTSD) to their care-experienced young people (children looked-after, adopted, or on special guardianship orders). The project primarily seeks to understand the process of implementation of the Child Revised Impact of Events Scale (CRIES-8) symptom measure and the tf-CBT intervention with care-experienced young people. This is captured via:
1. Anonymised service data (e.g., percentage of those referred who are screened using the CRIES-8; percentage of those who are offered tf-CBT), capturing the 3 months before the training and subsequently every 3 months, for a period of approximately 12 months;
2. Descriptive quantitative reports from therapists (tracking whether individual therapists are using the tools), and qualitative feedback from therapist focus groups and interviews around facilitators and barriers to using the screening tool and treatment. These data collected from therapists is collected 1 month after the training, and subsequently every 3 months for a period of approximately 12 months.

Key secondary outcome(s))
Current secondary outcome measures as of 28/04/2023:
The feasibility and pilot effectiveness component of the project explores key feasibility and acceptability questions, using mixed methods:
1. Qualitative feedback from service providers about the feasibility of referring young people to the study, along with descriptive numbers of eligible young people who are actually invited to the study, and then who participate.
2. Qualitative interviews with young people who were offered tf-CBT and their caregivers, at the post-treatment assessment. In addition, because not all young people offered tf-CBT will decide

to be involved in the trial, we will also draw on service data to understand how many young people are offered the intervention and general retention rates;
3. Measure symptom change from pre- to post-treatment and 3-monthly follow-up. The primary outcomes assessed at these timepoints are PTSD symptom severity and complex PTSD symptom severity (both measured via the Child & Adolescent Trauma Screen-2) and/or the routinely collected Children's Revised Impact of Event Scale (CRIES-8). The secondary outcomes assessed at these timepoints are symptom change on:
3.1. The young person's self-reported anxiety and depression (Revised Child Anxiety and Depression Scale), perceived support (Multidimensional Perceived Support Scale) and quality of life (Investigating Choice Experiments for the preferences of people CAPability);
3.2. The carer's report of the child's symptoms, relationship quality (Relationship Problems Questionnaire) and general wellbeing (Strengths and Difficulties Questionnaire; KINDL questionnaire of young people's quality of life), and the carer's own mental health (Depression, Anxiety and Stress Scale).
3.3. A third component will explore whether tf-CBT was associated with change (assessed at the same timepoints) in key proposed target mechanisms, spanning child report of their maladaptive cognitions (Child Post-Traumatic Cognitions Inventory), memory quality (Adapted Child Trauma Memory Questionnaire), and avoidant coping (Child Posttrauma Cognitive Coping Scale).

Previous secondary outcome measures:
The feasibility and pilot effectiveness component of the project explores key feasibility and acceptability questions, using mixed methods:
1. Qualitative feedback from service providers about the feasibility of referring young people to the study, along with descriptive numbers of eligible young people who are actually invited to the study, and then who participate.
2. Qualitative interviews with young people who were offered tf-CBT and their caregivers, at the post-treatment assessment. In addition, because not all young people offered tf-CBT will decide to be involved in the trial, we will also draw on service data to understand how many young people are offered the intervention and general retention rates;
3. Measure symptom change from pre- to post-treatment and at 3-month follow-up. The primary outcomes assessed at these timepoints are PTSD symptom severity and complex PTSD symptom severity (both measured via the Child & Adolescent Trauma Screen-2). The secondary outcomes assessed at these timepoints are symptom change on:
3.1. The young person's self-reported anxiety and depression (Revised Child Anxiety and Depression Scale) and perceived support (Multidimensional Perceived Support Scale);
3.2. The carer's report of the child's symptoms, relationship quality (Relationship Problems Questionnaire) and general wellbeing (Quality of Life Questionnaire for Children), and the carer' s own mental health (Depression, anxiety and stress scale).
3.3. A third component will explore whether tf-CBT was associated with change (assessed at the same timepoints) in key proposed target mechanisms, spanning child report of their maladaptive cognitions (Child Post-Traumatic Cognitions Inventory), memory quality (Adapted Child Trauma Memory Questionnaire), and avoidant coping (Child Posttrauma Cognitive Coping Scale).

Completion date
31/12/2023

Eligibility

Key inclusion criteria
Services:
Any service that provide mental health interventions to care-experienced young people,

including CAMHS and specialist CAMHS. For feasibility, this primarily targets specialist looked-after children CAMHS or teams within CAMHS who specialise in the assessment and management of care-experienced young people. The participants are the mental health service providers within the participating services, who complete training in the tf-CBT.

Young people:
1. A care-experienced young person, which includes three specific categories: (i) a young person under the care of a local authority (Looked-after child), (ii) a young person adopted from care, or (iii) a young person on a special guardianship order.
2. Aged 8yrs - 17yrs 11mo
3. Attending a participating mental health service and been offered a trauma-focused CBT
4. Have adequate English skills and intellectual capacity to complete questionnaires (based on clinician and care-giver judgment)

The young person's primary caregiver will also be invited to participate. They can decline and the young person can still participate (but not visa versa).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
8 years

Upper age limit
18 years

Sex
All

Key exclusion criteria
As this is a naturalistic case study of implementation, there are no exclusion criteria for the young person that can access the intervention. The clinician ultimately decides whether or not to screen the young person for PTSD and whether or not to provide the treatment (which then makes the young person eligible for our study), based on their clinical judgment. Via service data collation and qualitative interviews with service providers, we will gather information on what groups of young people they choose not to provide the treatment to and why.

Date of first enrolment
30/06/2022

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
St Nicholas Hospital
Jubilee Road
Gosforth
Newcastle upon Tyne
United Kingdom
NE3 3XT

Study participating centre
Tees, Esk and Wear Valleys NHS Foundation Trust
Trust Headquarters
West Park Hospital
Edward Pease Way
Darlington
United Kingdom
DL2 2TS

Study participating centre
Hertfordshire Partnership University NHS Foundation Trust
The Colonnades
Beaconsfield Close
Hatfield
United Kingdom
AL10 8YE

Study participating centre
Norfolk and Suffolk NHS Foundation Trust
Hellesdon Hospital
Drayton High Road
Norwich
United Kingdom
NR6 5BE

Study participating centre

Tavistock and Portman NHS Foundation Trust
The Tavistock Centre
120 Belsize Lane
London
United Kingdom
NW3 5BA

Study participating centre
Whittington Health NHS Trust
The Whittington Hospital
Magdala Avenue
London
United Kingdom
N19 5NF

Study participating centre
Central and North West London NHS Foundation Trust
Trust Headquarters
350 Euston Road
Regents PLACE
London
United Kingdom
NW1 3AX

Study participating centre
Devon Partnership NHS Trust
Wonford House Hospital
Dryden Road
Exeter
United Kingdom
EX2 5AF

Study participating centre
Cornwall Partnership NHS Foundation Trust
Carew House
Beacon Technology Park
Dunmere Road
Bodmin
United Kingdom
PL31 2QN

Study participating centre
Sussex Partnership NHS Foundation Trust
Trust Hq
Swandean
Arundel Road
Worthing
United Kingdom
BN13 3EP

Study participating centre
Solent NHS Trust
Solent NHS Trust Headquarters
Highpoint Venue
Bursledon Road
Southampton
United Kingdom
SO19 8BR

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Individual participant data (IPD) sharing plan
Due to the sensitive nature of the data and the need to carefully consult all organisations involved, the data sharing plans for the current study are currently unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes