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Online post-traumatic stress disorder treatment for young people and their carers

Submission date
02/07/2020

Recruitment status
No longer recruiting

Registration date
06/07/2020

Overall study status
Completed

Last Edited
05/08/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Many teenagers will be exposed to a potentially traumatic event at some point before they are 18 years old, and many of them will develop post-traumatic stress disorder (PTSD). PTSD is distressing and often causes problems at home and at school. Cognitive therapy for PTSD is very effective when young people can go to regular weekly face-to-face appointments to see a trained therapist. However, face-to-face therapy is sometimes not offered to young people due to a shortage of trained therapists, and some young people cannot attend the clinic for many reasons. This means that many young people with PTSD miss out on effective treatments. Researchers have developed a progressive web app to deliver cognitive therapy to young people with PTSD with a smartphone, tablet or computer. They want to find out what young people and their carers or parents think of this way of delivering therapy. They want to find out how easy it is to recruit young people and to engage them in the treatment to inform a larger trial in the future. They also want to see whether symptoms of PTSD and other problems such as depression and anxiety reduce after doing the therapy and how this compares to natural recovery.

Who can participate?
Young people (aged 12-17 years) whose main presenting problem is PTSD following a single-event trauma (e.g. serious accidents or assaults)

What does the study involve?
Participants are randomly allocated to either receive online therapy to receive delayed treatment, where they will wait 16 weeks before receiving the online treatment. Face-to-face therapy will be offered to young people allocated to the waitlist condition if clinics are running as usual and offering face-to-face appointments following the COVID-19 pandemic. The online treatment involves therapist-supported online delivery of all components from a face-to-face CT manual, including psycho-education, reclaiming life, developing a narrative of the trauma, re-appraisal of trauma-related cognitions, updating the trauma memory, stimulus discrimination training, developing a relapse-prevention blueprint. Work with parents is via a parallel parent App. Young people are supported to complete their treatment via a weekly phone call from their therapist. The researchers will carry out detailed assessments before and after treatment to see if symptoms are reduced after doing the therapy, and how symptom improvement compares

across the two groups. These will be repeated at 38 weeks (follow-up) for the active treatment group only to see if any treatment effects are long-lasting.

What are the possible benefits and risks of participating?
Sometimes this therapy, whether delivered face-to-face or online, may be upsetting. However, a therapist will be available throughout treatment to support young people if this happens. In addition, the online therapy has already been used by some young people. They did not experience any disadvantages or risks in using the online therapy. There is a 50% chance young people will be allocated to the delayed treatment group. This means that they will be asked to wait for 16 weeks before receiving the online therapy. The researchers may also be able to offer young people face-to-face treatment after the 16-week wait, if preferred, and if clinics are running normally at the time. Young people can seek support from their GP if they feel they need support while waiting for treatment to begin. The evidence so far shows that young people are likely to be helped by receiving treatment through this study. Young people will have a 50% chance of being allocated to online therapy without having to wait. The researchers think that the online therapy will be effective in treating PTSD. Face-to-face cognitive therapy for PTSD has been shown to be is very effective, and the researchers have designed the new online therapy using the same treatment components as this treatment.

Where is the study run from?
King’s College London (UK)

When is the study starting and how long is it expected to run for?
June 2020 to July 2022

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Dr Patrick Smith
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Study website
https://www.optyc.org/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
262807

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 262807, CPMS 42768

Study information

Scientific Title
Internet-delivered cognitive therapy (iCT) for young people with post-traumatic stress disorder (PTSD) - early-stage randomized controlled trial

Acronym
OPTYC

Study objectives
This is an early stage trial with two arms: a newly developed internet-delivered Cognitive Therapy (iCT) programme to treat PTSD in adolescents, and a Wait List condition. The objectives of the RCT are to: provide feasibility data on acceptability, compliance, retention, and delivery; and to provide initial estimates of the effect of iCT on symptoms of PTSD, anxiety and depression relative to a wait-list condition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/06/2020, London Bridge Research Ethics Committee (Skipton House, 80 London Road London SE1 6LH, UK; +44 (0)207 104 8019; londonbridge.rec@hra.nhs.uk), REC ref: 19/LO/1354

Study design
Two-arm parallel-group single-blind (outcome assessor) early-stage randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
Randomisation will be carried out by an independent clinical trials unit. Individual patient-level randomisation, with allocation in a 1:1 ratio, using minimisation methods employing two factors (gender and symptom severity), will be used to randomise into one of two arms:

1. Internet-delivered Cognitive Therapy (iCT; n = 17)
This comprises therapist-supported online delivery of all components from our face-to-face Cognitive Therapy (CT) manual (Smith et al., 2010), including: psycho-education, reclaiming life, developing a narrative of the trauma, re-appraisal of trauma-related cognitions, updating the trauma memory, stimulus discrimination training, developing a relapse-prevention blueprint. Young people are supported to complete treatment via a weekly phone call from their therapist. There is a separate online programme for parents and carers.

2. Wait List (WL; n = 17)
Patients allocated to WL will be asked to wait for 16 weeks before being offered iCT. If preferred, and if clinics are open and functioning as usual at the time, patients will be able to opt for face-to-face CT-PTSD after the 16-week wait.

Assessments will take place at pre-treatment (0 weeks), mid-treatment (6 weeks post-randomisation), post-treatment (16 weeks post-randomisation), and at follow-up (38 weeks post-randomisation). Follow up assessments at 38 weeks will be conducted for the iCT arm only.

Intervention Type
Behavioural

Primary outcome measure
As this is an early-stage trial, the primary outcomes are feasibility outcomes and adherence metrics. Feasibility data on acceptability, compliance, retention, and delivery will be collected to enable an estimation of key parameters to inform a larger trial. This is in line with MRC guidance.

The following feasibility data on acceptability will be collected during the trial recruitment phase at the pre-intervention assessment and during the randomisation phase (June 2020- August 2021):
1. The total number of young people referred to the trial by (i) schools, (ii) Child and Adolescent Mental Health Services (CAMHS), or (iii) GP or self-referral

2. Number of young people screened in schools, and of these, the proportion who are considered to be eligible at school and proceed to a phone call with family
3. Number and proportion of young people in schools scoring above cut-off on a validated screening questionnaire (a score of ≥17 on the Children's Revised Impact of Event Scale, CRIES-8); relative to the number of young people screened in schools
4. The number and proportion of young people in schools who score above cut-off on the CRIES-8 but decline further participation with the trial (relative to those scoring above cut-off)
5. The number and proportion of young people in schools who score above cut-off on CRIES-8 and consent to further assessment but are deemed ineligible at baseline assessment (relative to those deemed eligible at baseline assessment)
6. Number of assessment appointments offered to participants (via any referral route)
7. Number and proportion of assessment appointments attended by participants, relative to the number of appointments offered, reported by referral source (schools, CAMHS, GP referral, and self-referral)
8. Reasons for not attending assessment appointments (count and percentages) reported by referral source (schools, CAMHS, GP referral, and self-referral)
9. Number and proportion of young people who, at the baseline assessment, consent to participation in the trial (number consented / number attended assessment). Reasons for not consenting if known (count and percent)
10. Number and proportion of young people eligible for the trial after baseline assessment (number eligible at baseline interview/number assessed for eligibility at baseline interview)
11. Number of young people who are randomised, and proportion of consented young people who are randomised (number randomised / number consented)
12. Reasons for withdrawing from the trial if known
13. Number retained in study at 16 weeks (post-treatment) and at 38 weeks (follow-up), and proportions of those who start treatment that are retained (number retained / number started, and number retained/number randomised), by arm

Acceptability will also be gauged by carrying out qualitative interviews with young people about the acceptability of the research procedures, the assessment measures and views of randomisation at 16 weeks (post-treatment).

The following feasibility data on adherence, compliance and delivery will be collected in the iCT arm throughout the treatment phase (0-12 weeks):
14. Number of times logged into the programme per week and in total
15. Time spent logged in per week and in total
16. Number of modules completed in total and according to device used (phone, tablet, computer)
17. Number of therapist phone calls attended per week and in total, and the number of missed phone appointments
18. Time spent on phone calls per week and in total
19. Number of messages to/from therapist per week and in total
20. Number and proportion of young people who start treatment (number starting treatment /number randomised)
21. Number of weeks of therapy completed
22. Reasons for dropping out of treatment if known

Feasibility data on retention will be collected, including the reasons for withdrawing from the trial, if known and the number retained in the study at 16 weeks (post-treatment) and at 38 weeks (follow-up), and proportions of those who start treatment that are retained (number retained / number started, and number retained/number randomised), by arm.

The primary clinical outcome is the presence or absence of a diagnosis of post-traumatic stress disorder (PTSD) according to the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) published by the American Psychiatric Association, determined using a gold-standard semi-structured clinical interview: the Clinician-Administered PTSD Scale for DSM-5 - child and adolescent version (CAPS-5-CA), administered at 0 and 16 weeks after randomisation. This is a clinician-administered interview and will be administered by trained, reliable raters who are blind to treatment allocation.

Secondary outcome measures

Current secondary outcome measures as of 23/11/2021:

Young person completed outcome measures:
1. PTSD symptom severity measured using the CAPS-CA-5 at 0 (baseline) and 16 weeks post-randomisation (post intervention)
2. PTSD symptoms measured using the Child Post Traumatic Stress Scale (CPSS-5) and at 0, 16 and 38 weeks post randomisation (follow up)
3. Re-experiencing the traumatic event and avoidance measured using the Children's Revised Impact of Event Scale - 8 item version (CRIES-8) at 0, 6, 16, and 38 weeks
4. Anxiety and depression measured using the Revised Children's Anxiety and Depression Scale (RCADS-C) at 0, 16 and 38 weeks

Parent/carer completed outcome measures:
5. Emotional and behavioural problems measured using the Strength & Difficulties Questionnaire (SDQ-P) at 0, 16 and 38 weeks
6. Depression and anxiety measured using the Revised Children's Anxiety and Depression Scale (RCADS-P) at 0, 16 and 38 weeks

Process measures
7. Negative trauma-related cognitions and appraisals measured using the Child Post Traumatic Cognitions Inventory (CPTCI) at 0, 6, 16 and 38 weeks
8. Memory quality measured using the Trauma Memory Quality Questionnaire (TMQQ) at 0, 6, 16 and 38 weeks
9. Rumination measured using the Trauma Related Rumination Questionnaire items at 0, 6, 16 and 38 weeks

Health economic measures
10. Health economics measured using the Child & Adolescent Service Use Schedule (CA-SUS) at 0, 16 and 38 weeks
11. Health-related quality of life using the Child Health Utility Index 9D (CHU-9D) measured at 0, 16 and 38 weeks

These outcomes will only be repeated at 38 weeks post-randomisation (follow-up) in the RCT for the active treatment arm

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Previous secondary outcome measures:

Young person completed outcome measures:
1. PTSD symptom severity measured using the CAPS-CA-5 at 0 (baseline) and 16 weeks post-randomisation (post intervention)
2. PTSD symptoms measured using the Child Post Traumatic Stress Scale (CPSS-5) and at 0, 16

and 38 weeks post randomisation (follow up)
3. Re-experiencing the traumatic event and avoidance measured using the Children's Revised Impact of Event Scale - 8 item version (CRIES-8) at 0, 6, 16, and 38 weeks
4. Anxiety and depression measured using the Revised Children's Anxiety and Depression Scale (RCADS-C) at 0, 16 and 38 weeks
5. Negative trauma-related cognitions and appraisals measured using the Child Post Traumatic Cognitions Inventory (CPTCI) at 0, 6, 16 and 38 weeks
6. Health-related quality of life using the Child Health Utility Index 9D (CHU-9D) measured at 0, 16 and 38 weeks

Parent/carer completed outcome measures:
7. Emotional and behavioural problems measured using the Strength & Difficulties Questionnaire (SDQ-P) at 0, 16 and 38 weeks
8. Depression and anxiety measured using the Revised Children's Anxiety and Depression Scale (RCADS-P) at 0, 16 and 38 weeks
9. Health economics measured using the Child & Adolescent Service Use Schedule (CA-SUS) at 0, 16 and 38 weeks

These outcomes will only be repeated at 38 weeks post-randomisation (follow-up) in the RCT for the active treatment arm

Overall study start date
01/12/2017

Completion date
19/07/2022

Eligibility

Key inclusion criteria
Young people:
1. Aged 12-17 years old
2. Main presenting problem is PTSD (diagnosed using CAPS-5-CA) and there is a not a co-morbid problem that would preclude treatment of PTSD
3. PTSD symptoms relate to a single trauma
4. Participant has access to compatible smartphone or larger computing device (e.g. laptop, desktop computer, iPad) with internet access and to a safe and confidential space in which to engage in iCT
5. Participant speaks English to a level that allows therapy without the need for an interpreter, and reads English to a level that allows independent use of iCT

Parents or carers:
1. Parent or carer of a young person who meets all of the inclusion criteria above and none of the exclusion criteria below
2. Parent or carer speaks English to a level that allows participation in therapy without the need for an interpreter, and reads English to a level that allows independent use of iCT
3. Parent or carer has access to compatible smartphone or larger computing device (e.g. laptop, desktop computer, iPad) with internet access

Participant type(s)
Patient, Carer

Age group
Mixed

Sex
Both

Target number of participants
34

Total final enrolment
31

Key exclusion criteria
Young people:
1. Brain damage
2. Intellectual disability
3. Pervasive developmental disorder or neurodevelopmental disorder
4. Other psychiatric diagnosis that requires treatment before PTSD
5. Moderate to high risk to self
6. Ongoing trauma-related threat
7. Started treatment with psychotropic medication, or changed medication, within the last 2 months
8. Currently receiving another psychological treatment
9. Has already received trauma-focused CBT in relation to the same traumatic event that they are currently seeking treatment for

Parents or carers:
Parents or carers are not eligible if their son or daughter meets the exclusion criteria above. There are no additional exclusion criteria for parents or carers

Date of first enrolment
14/07/2020

Date of final enrolment
01/11/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Maudsley Hospital
South London and Maudsley NHS Foundation Trust
Denmark Hill
London

United Kingdom
SE5 8AZ

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

Study participating centre
Erlegh House
Berkshire Health NHS Foundation Trust
University of Reading
Reading
United Kingdom
RG6 6BZ

Study participating centre
Warneford Hospital
Oxford Health NHS Foundation Trust
Warneford Lane
Headington
Oxford
United Kingdom
OX3 7JX

Study participating centre
NELFT NHS Foundation Trust
651 The Crescent
Colchester Business Park
Colchester
United Kingdom
CO4 9YQ

Study participating centre
Northern Health Centre
Whittington Health NHS Foundation Trust
580 Holloway Road
London

United Kingdom
N7 6LB

Study participating centre
Fulbourn Hospital
Cambridge and Peterborough NHS Foundation Trust
Elizabeth House
Cambridge Road
Cambridgeshire
United Kingdom
CB21 5EF

Study participating centre
Memorial Hospital
OXLEAS NHS Foundation Trust
Highpoint House
Shooters Hill
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Sponsor information

Organisation
Joint Institute of Psychiatry, Psychology & Neuroscience and the South London and Maudsley NHS Foundation Trust.

Sponsor details
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+44 (0)20 7848 0790
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Sponsor type
University/education

Website
http://www.kcl.ac.uk/index.aspx

ROR
https://ror.org/015803449

Funder(s)

Funder type
Government

Funder Name
Medical Research Council Developmental pathway Funding Scheme (DPFS) MRC reference: MR /P017355/1

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The researchers will publish feasibility data and exploratory clinical outcome data from the randomized controlled trial. They will not provide details of case histories, and will not provide illustrative quotes from participants which contain information which may compromise anonymity. In presenting numerical data, we will ensure that no participant is identifiable.

A report will be prepared for the sponsor and funders.

The researchers plan to publish:
1. A peer-reviewed paper reporting the trial protocol
3. A peer-reviewed paper reporting the feasibility trial outcomes

They will also prepare a report on users' views on the iCT programme.

Intention to publish date
26/02/2023

Individual participant data (IPD) sharing plan

All investigators will have access to the final trial dataset. Our intentions are to maximise the availability and sharing of our data for the benefit of the wider research community, while providing for its long-term preservation and making due allowance for the potential commercial value of findings. The project management group will make the decision on whether to supply research data to a potential new researcher. Independent oversight of data access and sharing will be provided by the TSC. Data released to the wider community after publication will be fully anonymised.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	version 1.0	21/03/2022	09/08/2022	Yes	No
Statistical Analysis Plan		24/09/2021	11/08/2022	No	No
HRA research summary			28/06/2023	No	No
Results article		06/02/2025	05/08/2025	Yes	No