

Implementing internet-based cognitive therapy for post-traumatic stress disorder in NHS Improving Access to Psychological Therapies services

Submission date 05/09/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 13/09/2021	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 01/10/2021	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Posttraumatic stress disorder (PTSD) can develop after a range of traumatic events such as interpersonal violence, accidents, disaster or war zone experiences. Cognitive therapy for PTSD (CT-PTSD) is an effective treatment for this condition. A therapist-assisted internet-delivered version of this treatment (iCT-PTSD) has also been found to be acceptable to patients and effective in research studies. Patients complete online treatment modules that cover all components of CT-PTSD at a time and place convenient to them. A therapist guides them remotely through the treatment and supports them through messages and phone calls. The aim of this study is to investigate how effective iCT-PTSD is in routine clinical care and who benefits from it. The clinical outcomes of patients treated with iCT-PTSD will be assessed and compared to those previously observed in the services.

Who can participate?

1. People with posttraumatic stress disorder who receive treatment at one of the participating Improving Access to Psychological Therapies (IAPT) NHS services and agree to participate in the study
2. About 30 therapists from participating IAPT NHS services

What does the study involve?

For participating patients, the study involves completing the iCT-PTSD treatment programme online with the support of messages and phone calls with an IAPT therapist. It also involves completing questionnaires about symptoms, thoughts and ways of coping, and satisfaction with treatment.

Participating therapists will be trained to guide and support patients with PTSD in completing the iCT-PTSD treatment programme. They will then treat patients with PTSD with iCT-PTSD and receive supervision. At the end of the study, therapists complete a questionnaire and a focus group on their experience with delivering the treatment.

What are the possible benefits and risks of participating?

All participating patients will receive internet-based psychological therapy for PTSD with support from an IAPT therapist who has received specialist training and supervision. Undertaking treatment for PTSD can be challenging. Like in-person therapy, iCT-PTSD encourages participants to reflect on their difficulties in order to understand how PTSD works, and supports participants in tackling situations that they may have previously avoided. While doing this may temporarily increase distress, facing these challenges is an important step towards overcoming PTSD.

Where is the study run from?

The University of Oxford (UK)

When is the study starting and how long is it expected to run for?

April 2016 to December 2022

Who is funding the study?

The Wellcome Trust (UK) 200796/Z/16/Z

Who is the main contact?

Trinity de Simone

trinity.desimone@psy.ox.ac.uk

Contact information

Type(s)

Scientific

Contact name

Prof Anke Ehlers

ORCID ID

<http://orcid.org/0000-0002-8742-0192>

Contact details

Department of Experimental Psychology
University of Oxford
Centre for Anxiety Disorders and Trauma
Paradise Square
Oxford
United Kingdom
OX1 1TW
+44 (0)1865618600
anke.ehlers@psy.ox.ac.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

292312

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Version 2 23/02/2021, IRAS 292312, WT 200796/Z/16/Z, CPMS 49338

Study information

Scientific Title

A study of the implementation of Internet-based Cognitive Therapy for Post-Traumatic Stress Disorder within NHS Improving Access to Psychological Therapies (IAPT) services

Acronym

OVERCOME-PTSD

Study objectives

iCT-PTSD clinical outcomes will meet national IAPT targets for the treatment of common mental health disorders (i.e. at least 50% of patients recover, with many others showing reliable improvement).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 18/02/2021, London Brent Ethics Committee (80 London Road, Skipton House, London, SE1 6LH, UK; +44 (0)20 7104 8128, +44 (0)20 7104 8137; brent.rec@hra.nhs.uk), REC ref: 21/PR/103

Study design

Interventional multicenter implementation study

Primary study design

Interventional

Secondary study design

Non randomised study

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

Interventions

Cognitive therapy for PTSD (CT-PTSD) is a trauma-focused cognitive behavioural treatment for posttraumatic stress disorder recommended by NICE (2018) and international treatment guidelines. It is usually delivered in face-to-face sessions. A therapist-assisted internet-delivered version (iCT-PTSD) has recently been found to be efficacious and acceptable to patients. Patients are guided through the online treatment programme by a therapist. Patients work through the therapy modules of iCT-PTSD on a secure website, as well as completing treatment-related tasks and activities as part of their daily routine. The therapist releases the modules that are relevant to the patients and supports them through messages and phone calls. This study will evaluate the effectiveness of this treatment in IAPT services. IAPT therapists who consented to be part of the study, have been trained in iCT-PTSD and are receiving supervision. The total duration of treatment is up to 6 months, with a 3-month main treatment phase with weekly phone calls and a 3-month booster phase with monthly phone calls.

Intervention Type

Behavioural

Primary outcome measure

Recovery as defined in IAPT by cut-offs on the PTSD Symptom Checklist for DSM-5 (PCL-5) and Patient Health Questionnaire (PHQ-9) at the end of weekly treatment and the end of booster treatment

Secondary outcome measures

1. PTSD symptoms measured with the PCL-5 completed at baseline, 12 weeks and 24 weeks. The PCL-5 is given weekly during the weekly therapy phase as is standard in IAPT services
2. Depression symptoms measured with the PHQ-9 completed at baseline, 12 weeks and 24 weeks. The PHQ-7 is given weekly during the weekly therapy phase as is standard in IAPT services
3. Anxiety symptoms measured with the Generalised Anxiety Disorder Questionnaire (GAD-7) completed at baseline, 12 weeks and 24 weeks. The GAD-7 is given weekly during the weekly therapy phase as is standard in IAPT services
4. Disability measured with the Work and Social Adjustment Scale (WSAS) completed at baseline, 12 weeks and 24 weeks. The WSAS is given weekly during the weekly therapy phase as is standard in IAPT services
5. Satisfaction with treatment assessed with the IAPT Patient Experience Questionnaire at the end of treatment

Process measures:

1. Credibility of treatment measured with the Borkovec and Nau Credibility scale at 2 weeks.
2. Working alliance measured with the Working Alliance Scale completed by patients and therapists at 2 weeks
3. Appraisals of the trauma and its sequelae measured with a short version of the Posttraumatic Cognitions Inventory (PTCIs) given at baseline and weekly during the weekly therapy phase
4. Qualities of trauma memories measured with a short version of the trauma memory questionnaire (MQ) given at baseline weekly during the weekly therapy phase
5. Responses to intrusive memories measured with a short version of the Response to Intrusions Questionnaire (RIQ) given at baseline and weekly during the weekly therapy phase
6. Safety behaviours measured with a short version of the Safety Behaviours Questionnaire (SBQ) given at baseline and weekly during the weekly therapy phase
7. Dissociation measured with a short version of the Trait-State Dissociation Questionnaire

- (TDSQ) given at baseline and for those with high dissociation weekly during the weekly therapy phase
8. Sleep disturbance measured with the Insomnia Sleep Index (ISI) at baseline and for those with high sleep disturbance weekly during the weekly therapy phase
 9. Patient activity on the online programme such as time spent on the programme and modules completed, recorded during treatment

User experience with iCT-PTSD:

1. Therapists' experience with delivering iCT-PTSD assessed with the Therapist-Questionnaire-iCT-PTSD and focus group discussion at the end of the study
2. Patients' experience assessed through ratings of helpfulness and free comments provided at the end of each module

Overall study start date

01/04/2016

Completion date

31/12/2022

Eligibility

Key inclusion criteria

1. Post-Traumatic Stress Disorder is the main psychological problem, and the patient's priority to work on in therapy
2. Their current reexperiencing symptoms are linked to one or two discrete traumatic events that they experienced in adulthood or adolescence, or several traumatic episodes during a longer period of high threat (e.g., domestic abuse, war zone experiences)
3. Regular, private access to an internet-enabled device and reliable internet connection
4. Able to take phone calls from their therapist within normal IAPT clinic hours, and have enough time in their week to be able to log in and work on the programme regularly (i.e. at least 20 min on 3-4 days each week)
5. Able to speak, read and write English
6. If on medication for mood/anxiety, the participant agrees to remain to stay on a stable dose

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

360

Key exclusion criteria

1. Marked clinical risk based on the service's intake assessment
2. Current dependence on alcohol or substances
3. Currently participating in another clinical research study

4. Current psychosis/bipolar affective disorder/emotionally unstable personality disorder (NB. These conditions are not typically treated within IAPT services)

Date of first enrolment

18/02/2021

Date of final enrolment

30/09/2022

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

TalkingSpace Plus, Oxford Health

Abell House

Slade Site

Horspath Driftway

Oxford

United Kingdom

OX3 7JH

Study participating centre

Berkshire Talking Therapies IAPT Service

Fitzwilliam House

Skimped Hill Lane

Bracknell

United Kingdom

RG12 1QB

Study participating centre

First Step (IAPT) Access and Community CBU Cumbria, Northumberland, Tyne and Wear

Unit 26 Lillyhall Business Centre

Jubilee Road

Workington

United Kingdom

CA14 4HA

Study participating centre

Hertfordshire Partnership NHS Foundation Trust IAPT Services

SW Wellbeing Team
Prospect House, Peace Drive
Watford
United Kingdom
WD17 3XE

Study participating centre

iCope Camden and iCope Islington Psychological Therapies Service

South Wing
St Pancras Hospital
4 St Pancras Way
London
United Kingdom
NW1 0PE

Study participating centre

Healthy Minds - The Buckinghamshire IAPT Service

Floor 2, Prospect House
High Wycombe,
United Kingdom
HP13 6LA

Study participating centre

Health in Mind: Mid Essex

Tekhnicon House
Springwood Drive
Braintree
United Kingdom
CM7 2YN

Study participating centre

Back on Track IAPT Hammersmith & Fulham

194 Hammersmith Road
London
United Kingdom
W6 7DJ

Study participating centre

Ealing IAPT Services

84 Uxbridge Road

London
United Kingdom
W13 8RA

Study participating centre
Steps2change NHS Talking Therapies for Lincolnshire
The Archway Centre
Carlton Centre
Outer Circle Road
Lincoln
United Kingdom
LN2 4WA

Sponsor information

Organisation
University of Oxford

Sponsor details
Clinical Trials and Research Governance
Joint Research Office, 1st Floor Boundary Brook House
Churchill Drive
Headington
Oxford
England
United Kingdom
OX3 7GB
+44 (0)1865 (2)89885
ctrq@admin.ox.ac.uk

Sponsor type
University/education

Website
<http://www.ox.ac.uk/>

ROR
<https://ror.org/052gg0110>

Funder(s)

Funder type
Research organisation

Funder Name

Wellcome Trust

Alternative Name(s)

Wellcome, WT

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in peer-reviewed open access journal

Intention to publish date

30/09/2023

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are 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