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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

Registration date
13/09/2021

Overall study status
Completed

Last Edited
01/10/2021

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
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
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Contact information

Type(s)
Scientific

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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 Questonnaire (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
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LN2 4WA

Sponsor information

Organisation
University of Oxford

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OX3 7GB
+44 (0)1865 (2)89885
ctrg@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