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A randomised controlled trial of therapist-assisted online psychological therapies for post-traumatic stress disorder

Submission date
15/12/2017

Recruitment status
No longer recruiting

Registration date
05/01/2018

Overall study status
Completed

Last Edited
03/04/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Post-traumatic stress disorder (PTSD) is an anxiety disorder caused by very stressful, frightening or distressing events. Research shows that PTSD can be treated effectively with psychological treatments. However, many patients with PTSD are currently unable to access effective psychological treatments for a range of reasons, such as shortage of therapists, living too far away from treatment centres, or being unable to attend therapy during usual working hours. Given the large number of people suffering from PTSD, it is desirable to develop more efficient forms of treatment delivery that can be widely accessed, and online treatment delivery appears to be a promising alternative to face-to-face therapy. There is already some evidence that therapist-assisted online psychological treatments are effective in PTSD. The aim of this study is to compare two forms of therapist-supported internet-based psychological therapy for PTSD. The online therapies are based on effective face-to-face therapies (cognitive therapy, stress management therapy). Both treatments are compared with a wait-list to control for the natural recovery that is sometimes seen in PTSD.

Who can participate?
Patients aged 18 or above who suffer from PTSD resulting from traumatic events experienced in adulthood

What does the study involve?
Participants' symptoms of PTSD, depression, anxiety and functioning are assessed and they are randomly allocated to receive either one of the two internet-delivered psychological therapies immediately or after a delay of 13 weeks. The assessments are repeated at 6 weeks, the end of therapy/waiting, and 3, 6 and 12 months after the end of therapy. Therapy involves completing therapy modules online and assignments over 3 months, with guidance via messages and weekly phone calls with an experienced psychological therapist. An evaluation of the process of how symptoms change is treatment is also undertaken by collecting weekly questionnaires and by interviewing participants regarding their experiences.

What are the possible benefits and risks of participating?
All participants receive internet-delivered psychological therapy with support from a therapist for their PTSD. A team that specialises in the treatment of this disorder delivers the treatment and closely monitors progress. There is a 14% chance that participants are randomly selected to wait for 13 weeks before starting treatment. Some people may experience a temporary increase in distress as a result of remembering the trauma during treatment, but this is usually short-lived.

Where is the study run from?
1. University of Oxford (UK)
2. Institute for Psychiatry, Psychology and Neuroscience, King's College London (UK)
3. Oxford Health NHS Foundation Trust (UK)
4. South London and Maudsley NHS Foundation Trust (UK)
5. Sussex Partnership NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2017 to December 2021

Who is funding the study?
Wellcome Trust (UK)

Who is the main contact?
Miss Poppy Green, poppy.green@psy.ox.ac.uk

Study website
https://www.psy.ox.ac.uk/research/oxford-centre-for-anxiety-disorders-and-trauma/anxiety-disorders/post-traumatic-stress-disorder

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number
224759

ClinicalTrials.gov number

Secondary identifying numbers
REC 13041, IRAS 224759, Protocol Version 2, 25th November 2018, 200796/Z/16/Z

Study information

Scientific Title
A randomiSed controlled Trial of therapist-assisted Online Psychological therapies for Post-Traumatic Stress Disorder

Acronym
STOP-PTSD

Study objectives
Is internet-delivered cognitive therapy for PTSD more efficacious than internet-delivered stress-management for PTSD, i.e. does it lead to greater improvement in PTSD symptoms?

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - Black Country Research Ethics Committee, ref: 17/WM/0441

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Participants' symptoms of PTSD, depression, anxiety and functioning are assessed and they are randomised (minimisation with a random component) at a 3:3:1 ratio to either:
1. Internet-delivered cognitive therapy for PTSD (iCT-PTSD)
2. Internet-delivered stress-management for PTSD (iStress)
3. 13-week waitlist

The assessments are repeated at 6 weeks, the end of therapy/waiting, and 3, 6 and 12 months after the end of therapy. Therapy involves completing therapy modules online and assignments over 3 months, with guidance via messages and weekly phone calls with an experienced psychological therapists. An evaluation of the process of how symptoms change is treatment is also undertaken by collecting weekly questionnaires and by interviewing participants regarding their experiences.

Intervention Type
Behavioural

Primary outcome measure
PTSD symptoms measured with PTSD Symptom Checklist 5 at baseline, 6, 13 weeks after random allocation (with follow-ups at 26, 39 and 65 weeks), and weekly during treatment

Secondary outcome measures
1. Assessor ratings of PTSD symptoms, assessed with the Clinician Administered PTSD Scale for DSM 5 (CAPS-5) at baseline and 13 weeks after random allocation (with follow-ups at 26, 39 and 65 weeks).
2. Other symptom measures assessed at baseline, 6, 13 weeks after random allocation (with follow-ups at 26, 39 and 65 weeks), and weekly during treatment:
2.1. Depression, assessed with the Patient Health Questionnaire (PHQ-9)
2.2. Anxiety, assessed with the Generalized Anxiety Disorder Scale 7-items (GAD-7)
2.3. Disability, assessed with the Work and Social Adjustment Scale (WSAS)
2.4. Sleep problems, assessed with the Insomnia Sleep Index (ISI)
2.5 Well-being, assessed with the WHO-Five Wellbeing-Scale (added 05/11/2019)
2.6. Quality of life, assessed with the Endicott Quality of Life Scale (added 05/11/2019)
3. Health economics measures (Euroqol EQ-5D-5L12, iMTA Productivity Cost Questionnaire (PCQ), Endicott Quality of Life Scale (QoL), Client Service Receipt Inventory (CSRI), employment status and state benefits), assessed at baseline, 13, 26 and 39 weeks
4. Process measures assessed at baseline, 6, 13, 26, 39 weeks after random allocation (and some

weekly during treatment):
4.1. Excessively negative appraisals, assessed with the Posttraumatic Cognitions Inventory (PTCI), short version
4.2. Disjointed memories, assessed with the Trauma Memory Questionnaire (MQ), short version
4.3. Unhelpful strategies to deal with intrusive memories, assessed with the Response to Intrusion Questionnaire (RIQ)
4.4. Safety behaviours, assessed with the short version Safety Behaviours Questionnaire (SBQ)
4.5. Dissociation, assessed with the short version State-Trait Dissociation Questionnaire (TSDQ)
4.6. Self-efficacy, assessed with the short version Generalized Self Efficacy Scale (GSES)

Other process measures:
1. Therapeutic alliance, assessed using the Working Alliance Inventory (WAI) at weeks 2 and 6
2. Patient satisfaction and comments on their experience with online therapy, assessed using Online Treatment Experience Interview at week 13

Overall study start date
01/01/2017

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Aged 18 years and above
2. Diagnosis of Posttraumatic Stress Disorder (as assessed with the Structured Clinical Interview for DSM-5)
3. The current reexperiencing symptoms are linked to one or two discrete traumatic events experienced in adulthood.
Updated 05/11/2019: 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)
4. PTSD is the main psychological problem needing treatment
5. Willing and able to provide informed consent
6. Able to read and write in English
7. Access to internet
8. Willing to be randomly allocated to one of the psychological treatments or wait
9. If taking psychotropic medication, the dose must be stable for at least 1 month before randomisation
10. If currently receiving psychological therapy for PTSD, this treatment must have ended before randomisation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
217

Total final enrolment
217

Key exclusion criteria
1. History of psychosis
2. Current substance dependence
3. Current borderline personality disorder
4. Acute serious suicide risk

Date of first enrolment
15/01/2018

Date of final enrolment
31/03/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Study participating centre
Institute for Psychiatry, Psychology and Neuroscience, King's College London
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Study participating centre

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Study participating centre
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Sponsor information

Organisation
University of Oxford

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research organisation

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results will be published in peer-reviewed scientific journals with open access, as per Wellcome Trust policy

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
Given the sensitive nature of the study data, participants will be asked for optional consent to share their anonymised data with other researchers. For participants who consent to data-sharing, anonymised data will be available upon request from Prof. Anke Ehlers (anke.ehlers@psy.ox.ac.uk), after publication of the results of the trial and process analyses so that they can be used for meta-analyses or specified additional analyses.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		23/04/2020	11/08/2022	Yes	No
Preprint results		22/03/2023	30/03/2023	No	No
HRA research summary			28/06/2023	No	No
Results article		01/08/2023	24/07/2023	Yes	No
Other publications	Economic evaluation	26/03/2024	03/04/2024	Yes	No