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A study of trauma-focused online guided self help versus trauma-focused cognitive behavioural therapy for post-traumatic stress disorder

Submission date
21/12/2016

Recruitment status
No longer recruiting

Registration date
21/12/2016

Overall study status
Completed

Last Edited
21/11/2023

Condition category
Mental and Behavioural Disorders

✓ Prospectively registered
✓ Protocol added
? SAP not yet added
✓ Results added
? Raw data not yet added
✓ Study completed

Plain English Summary
Background and study aims
Post-traumatic stress disorder (PTSD) is a common, often disabling mental disorder that can occur following major traumatic events such as abuse, assaults and accidents. Typical symptoms include: distressing reliving in the form of nightmares or intrusive thoughts; avoidance of reminders; distorted thoughts such as feeling shame for being abused; and hyperarousal, for example through increased irritability and jumpiness. Recent news stories highlight the devastating impact that PTSD can have (e.g. the Savile Effect) and how the absence of timely intervention can lead to long-term suffering. They have also increased public awareness of PTSD and, potentially, the likelihood of presentation for help. The first choice treatments for PTSD are individual talking treatments (such as individual trauma-focused cognitive behavioural therapy, TFCBT) of 12-16 hours duration. Unfortunately, the limited number of therapists available and length of treatment means that there are long NHS waiting lists of up to 18 months. PTSD sufferers may also have difficulty committing to weekly appointments, especially if they are working, have childcare commitments or are scared to go out alone or to new places. If equally effective treatments could be developed that take less time and can be largely undertaken in a flexible manner at home, this would improve accessibility, reduce waiting times and hence the burden of disease. GSH has the potential to address this gap. The aim of this study is to find out whether trauma-focused guided self-help (GSH) using a web-based programme is an effective treatment for PTSD compared to TFCBT.

Who can participate?
Adults with PTSD following a single traumatic event

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in an eight week programme of the online guided self-help (GSH) programme using a web and app-based programme, with up to three hours contact with a therapist either in person, via internet

video link or telephone. Those in the second group will receive a 12 week programme of TFCBT, which involves weekly face-to-face sessions with a trained therapist. At the start of the study and then again after 16 and 52 weeks, participants in both groups complete a range of questionnaires to assess their mental wellbeing in order to establish the effectiveness of the treatments in treating their PTSD.

What are the possible benefits and risks of participating?
By taking part in the study, it is likely that participants will benefit from quicker access to therapy than on the NHS. Their involvement will also help the researchers to find out if GSH is a suitable and accessible treatment for people in the future, which may help to reduce waiting times for treatment and benefit patients in the future. A potential risk to taking part is an increase in psychological distress due to exposure to the trauma. However, this applies to any trauma focused therapy and the pilot (initial) study did not find any harms from the GSH intervention and none are expected in this study.

Where is the study run from?
Cardiff University (UK)

When is the study starting and how long is it expected to run for?
October 2016 to March 2021

Who is funding the study?
National Institute for Health Research Health Technology Assessment Programme (UK)

Who is the main contact?
Dr Paula Foscarini-Craggs
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Protocol/serial number
SPON 1545-16

Study information

Scientific Title
Pragmatic randomised controlled trial of a trauma-focused guided self help programme versus individual trauma-focused cognitive behavioural therapy for post traumatic stress disorder

Acronym
RAPID

Study hypothesis
Current hypothesis as of 13/09/2017:
The aim of this study is to determine whether, for patients with PTSD, an internet Trauma Focused Cognitive Behavioural Therapy (TFCBT) based Guided Self Help (GSH) programme is not inferior to individual TFCBT, as judged by reduced symptoms of PTSD at 16 weeks post-randomisation.

Previous hypothesis:
The aim of this study is to determine whether, for patients with PTSD, an internet Trauma Focused Cognitive Behavioural Therapy (TFCBT) based Guided Self Help (GSH) programme is not inferior to individual TFCBT, as judged by reduced symptoms of PTSD at 52 weeks post-randomisation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales REC 3, 23/02/2017, ref: 17/WA/0008

Study design
Phase III pragmatic assessor-blind individually-randomized controlled non-inferiority trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See study outputs table

Condition
Post-traumatic stress disorder following a single traumatic event

Interventions
Participants are randomised to one of two groups.

Intervention group: Participants receive Online Guided Self Help based on Trauma Focused Cognitive Behavioural Therapy (8 weeks)

Control group: Participants receive Face-to-face individual Trauma Focused Cognitive Behavioural Therapy (up to 12 weeks)

Participants in both groups are followed up 16 and 52 weeks post-randomisation.

Intervention Type
Behavioural

Primary outcome measure
Change in PTSD symtoms Clinician Administered PTSD Scale for DSM5 (CAPS-5) at 16 weeks.

Secondary outcome measures
1. PTSD symptoms, as measured using the Clinician-Administered PTSD Scale (CAPS-5) at 52 weeks post randomisation and Impact of Events Scale - Revised (IES-R) at 16 weeks and 52 weeks post-randomisation. IES-R is also completed at each therapy session.
2. Quality of life is measured using the EQ-5D-5L questionnaire at baseline, 16 and 52 weeks
3. Functional impairment is measured using the Work and Social Adjustment Scale (WSAS) at baseline, 16 and 52 weeks
4. Depression is measured using the Patient Health Questionnaire (PHQ-9) at baseline, 16 and 52 weeks
5. Anxiety symptoms are measured using the Generalized Anxiety Disorder 7-item (GAD-7) scale at baseline, 16 and 52 weeks
6. Alcohol use is measured using the AUDIT-O questionnaire at baseline, 16 and 52 weeks
7. Social Support is measured using the Multidimensional Scale of Perceived Social Support (MSPSS) at baseline, 16 and 52 weeks
8. Insomnia is measured using the Insomnia Severity Index (ISI) at baseline, 16 and 52 weeks
9. Self-efficacy is measured using the General Self-Efficacy Scale (GSES) at baseline, 16 and 52 weeks
10. Cognition is measured using the Posttraumatic Cognitions Inventory (PTCI) at baseline, 16 and 52 weeks
11. Health care usage using an adapted version of the CSSRI-EU at baseline, 16 and 52 weeks

Overall study start date
01/10/2016

Overall study end date

31/03/2021

Eligibility

Participant inclusion criteria
1. Aged 18 years or over
2. Screen positive for PTSD on the Traumatic Screening Questionnaire (TSQ) following a single traumatic event experienced at any age
3. Regular access to the internet in order to complete the modules and homework required by the Guided Self Help (GSH) programme
4. Provide informed consent
5. After a two week monitoring period, continue to meet Clinician Administered PTSD Scale (CAPS-5) criteria for mild to moderate PTSD (less than 50 on the CAPS-5)
6. PTSD is the primary diagnosis

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
192

Total final enrolment
196

Participant exclusion criteria
1. Inability to read and write fluently in English
2. Previous completion of a course of Trauma-focused Cognitive Behavioural Therapy (TFCBT) for PTSD
3. Currently engaged in a psychological therapy
4. Change in psychotropic medication in last four weeks
5. Psychosis
6. Substance dependence
7. Active suicide risk

Recruitment start date
29/08/2017

Recruitment end date
31/12/2019

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cardiff University
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CF10 3AT

Sponsor information

Organisation
Cardiff University

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Sponsor type
University/education

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ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Promotion of the trial will occur throughout the study through study webpages, social media, local and national media. The results will be presented to the participants through an end of study report and published in high quality, open access journals.

Intention to publish date
31/03/2022

Individual participant data (IPD) sharing plan
The current 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V3.0	21/02/2017	13/09/2017	No	Yes
Protocol article	protocol	27/03/2018		Yes	No
Results article		16/06/2022	17/06/2022	Yes	No
HRA research summary			28/06/2023	No	No
Results article		01/11/2023	21/11/2023	Yes	No