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Does a phased approach enhance outcomes for trauma-focused cognitive therapy for complex posttraumatic stress disorder?

Submission date
02/03/2023

Recruitment status
No longer recruiting

Registration date
07/03/2023

Overall study status
Ongoing

Last Edited
16/07/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Cognitive Therapy for Posttraumatic Stress Disorder (CT-PTSD) is a NICE-recommended psychological therapy that has been shown to be effective and acceptable to patients in many research studies and clinical audits. Complex PTSD is a new diagnosis introduced into the diagnostic manual of the World Health Organisation (ICD-11) to characterise people who have unwanted memories of traumas, avoidance of reminders, high arousal and problems with emotion regulation, a negative view of themselves and problems maintaining relationships. This study aims to investigate how effective CT-PTSD is in clients treated across a wide range of services across Northern Ireland and England. The study will compare the delivery of CT-PTSD with and without a phased element. In one group, the treatment involves the immediate provision of CT-PTSD, which is adapted individually to each patient, and in the other group CT-PTSD is provided after eight sessions of compassionate resilience training (phased CT-PTSD). The study will consider whether both approaches work equally well or whether there are advantages in providing a phased approach or a non-phased approach for some groups of clients.

Who can participate?
Patients aged 18 years and above with complex PTSD

What does the study involve?
Participants who are eligible and wish to take part in the study will (after consent) be randomly allocated to one of two groups (phased or non-phased). Treatment in the trial involves 24 treatment sessions and regular assessments that measure progress during therapy and at follow-up time points. Questionnaires will be completed at the eligibility assessment, after 9 and 17 weeks of treatment, at the end of therapy (26 weeks) and 3 months (39 weeks) and 6 months after the end of therapy (52 weeks). These sets of questionnaires will take about 30 to 60 minutes to complete. Some of the questionnaires will also be given regularly during treatment to help the therapist with planning treatment sessions. At 2 and 10 weeks, participants will be asked some brief questions about their thoughts on the treatment. In addition, independent assessors will interview participants at the eligibility stage, end of treatment (26 weeks) and 6 months later (52 weeks). In total, your involvement with the study will be for 1 year.

What are the possible benefits and risks of participating?
Participants will be offered an evidence-based treatment for PTSD with or without a phased element under the supervision of experienced supervisors and trainers in CT-PTSD and Compassionate Resilience Training. Participants will be able to avail of one of these therapies under the controlled scrutiny and high standards required for a randomised controlled trial. Participation in this study also has the potential to make a valuable contribution to existing research on treatments for Complex PTSD.
With regard to risk, participant wellbeing is paramount and protocols are in place to ensure participants feel safe and support. Should a participant find any aspects of the study distressing, there will be a discussion around how the therapy will be adapted around the individual's needs.

Where is the study run from?
The PHASE-CPTSD study is a collaboration between Queens University Belfast, the University of Oxford and ten HSC and NHS Foundation Trusts across Northern Ireland and England (UK)

When is the study starting and how long is it expected to run?
June 2020 to September 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
1. Dr Michael Duffy, michael.duffy@qub.ac.uk
2. Prof. Anke Ehlers, anke.ehlers@psy.ox.ac.uk

Contact information

Type(s)
Principal Investigator

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
309119

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 58088, IRAS 309119, Protocol version 1 11th November 2022 Internal Reference (Sponsor – Queen’s University Belfast): B22/21

Study information

Scientific Title
Does a PHASEd approach enhance outcomes for trauma-focused cognitive therapy for Complex Post-Traumatic Stress Disorder?

Acronym
PHASE-CPTSD

Study objectives
1. Is phased Cognitive Therapy for Posttraumatic Stress Disorder (CT-PTSD) superior to non-phased CT-PTSD in terms of acceptability, compliance and satisfaction with treatment?
2. Is phased CT-PTSD superior to non-phased CT-PTSD in improving symptoms of CPTSD, depression, anxiety, disability, well-being, and quality of life?
3. Is phased CT-PTSD cost-efficient compared to non-phased CT-PTSD in terms of cost per participant with a clinical improvement in PTSD symptoms and costs per quality-adjusted life year (QALY) gained?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/01/2023, South Central - Berkshire B Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)2071048276; berkshireb.rec@hra.nhs.uk), ref: 22/SC/0466

Study design
Multicentre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other therapist office, Telephone, University/medical school/dental school

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
Complex Post-Traumatic Stress Disorder (CPTSD)

Interventions
Approximately even numbers are allocated to the two treatment arms, phased CT-PTSD and non-phased CT-PTSD; allocation is stratified based on site, CPTSD symptom severity, age at main trauma (<18 years vs 18 years and above) and need for a translator (yes vs no); the randomization sequence is not visible to the research staff who generate the treatment randomization with the programme to ensure allocation concealment.

CT-PTSD is a NICE-recommended first-line treatment for PTSD. It addresses distressing trauma memories and their meanings as well as unhelpful ways of coping. 24 sessions will be offered. Outcomes will be assessed at baseline and 9, 17, 26, 39 and 52 weeks after randomization.

In phased CT-PTSD, 16 sessions of this treatment are offered after 8 weeks of compassionate resilience training. Outcomes will be assessed at the same time points as for non-phased CT-PTSD.

Intervention Type
Behavioural

Primary outcome measure
1. Complex PTSD symptom severity, as assessed by the International Trauma Questionnaire (ITQ) at 26 weeks post-randomisation.
2. PTSD symptom severity also measured by:
1.1. ITQ at 9, 17, 39 and 52 weeks
1.2. International Trauma Interview (ITI) at 26 and 52 weeks
1.3. Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5) at 9, 17, 39 and 52 weeks

Secondary outcome measures
1: Depression measured using the Patient Health Questionnaire (PHQ-9) at weeks 9, 17, 26, 39 and 52
2. Anxiety measured using the Generalized Anxiety Disorder 7-item (GAD-7) at weeks 9, 17, 26, 39 and 52
3. Disability measured using the Work and Social Adjustment Scale (WSAS) at weeks 9, 17, 26, 39 and 52
4: Well-being measured using the WHO (Five) Well-Being Index at weeks 9, 17, 26, 39 and 52
5. Quality of Life measured using the Endicott Quality of Life (QoL) Scale at 9, 26, 39 and 52 weeks
6. Credibility and outcome expectancy measured using the Borkovec and Nau's Credibility /Expectancy (CES) Scale at 2 and 10 weeks
7. Attendance and adherence to interventions measured using therapist report at week 26
8. Drop-outs from treatment and reasons measured using [method/data source] treatment log and CTU database at 26 weeks
9. Patient experience of therapy measured using the IAPT Patient Experience Questionnaire (PEQ) at 26 weeks

Overall study start date
01/06/2020

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Aged 18 years and above
2. Willing and able to provide informed consent
3. Meets ICD-11 diagnostic criteria for CPTSD as determined by the International Trauma Interview (ITI)
4. CPTSD is the main psychological problem needing treatment
5. Willing to be randomized to a treatment arm
6. If taking psychotropic medication, the dose must be stable for at least 1 month before randomization to a treatment arm

7. If currently receiving psychological therapy for CPTSD, this treatment must have ended before being randomized to a treatment arm

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Approximately 350 participants across 10 research sites

Total final enrolment
117

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

Date of first enrolment
01/04/2023

Date of final enrolment
30/06/2024

Locations

Countries of recruitment
England

Northern Ireland

United Kingdom

Study participating centre
Northern Health and Social Care Trust
The Cottage
5 Greenmount Avenue
Ballymena
Co. Antrim
United Kingdom
BT43 6DA

Study participating centre
Western Health and Social Care Trust
Mdec Building
Altnagelvin Area Hospital Site
Glenshane Road
Londonderry
United Kingdom
BT47 6SB

Study participating centre
Southern Health and Social Care Trust
Craigavon Area
Hospital
68 Lurgan Road
Portadown
Co. Armagh
United Kingdom
BT63 5QQ

Study participating centre
South Eastern Health and Social Care Trust
Thompson House Hospital
19/21 Magheralave Road
Co. Antrim
United Kingdom
BT28 3BP

Study participating centre
Belfast Health and Social Care Trust
Knockbracken Healthcare Park
Saintfield Road
Belfast
United Kingdom
BT8 8SG

Study participating centre
Talkingspace Plus
Oxbridge Court
Osney Mead
Oxford

United Kingdom
OX2 0ES

Study participating centre
Healthy Minds
2nd Floor
Prospect House
Crendon Street
High Wycombe
United Kingdom
HP13 6LA

Study participating centre
Islington iCope
10 Manor Gardens
London
United Kingdom
N7 6ER

Study participating centre
Traumatic Stress Clinic Camden
4th Floor, West Wing
St Pancras Hospital
4 St Pancras Way
United Kingdom
NW1 0PE

Study participating centre
South West London and St George's IAPT Services - Merton Uplift
Cricket Green Medical Practice
2nd Floor
75-79 Miles Rd
Mitcham
United Kingdom
CR4 3DA

Study participating centre
South West London and St George's IAPT Services - Sutton Uplift
Jubilee East Health Centre
1st Floor
6 Stanley Park Road

Wallington
United Kingdom
SM6 0EX

Study participating centre
South West London Traumatic Stress Specialist Service
Springfield University Hospital
Elizabeth Newton Building
Trinity Building, Springfield University Hospital
15 Springfield Drive
London
United Kingdom
SW17 0YF

Study participating centre
Berkshire Traumatic Stress Service
University of Reading
Whiteknights
Reading
United Kingdom
RG6 6BZ

Study participating centre
Op Courage - Veterans Mental Health service Berkshire Healthcare Trust
University of Reading
Whiteknights
Reading
United Kingdom
RG6 6BZ

Study participating centre
Hertfordshire Wellbeing (IAPT) Service
99 Waverley Road
St Albans
United Kingdom
AL3 5TL

Study participating centre
Mid-Essex IAPT Service
Tekhnicon House
Springwood Drive

Braintree
United Kingdom
CM7 2YN

Study participating centre
South Bucks Psychological Therapies
South Buckinghamshire Community Mental Health Hub
Saffron House
Easton Street
High Wycombe
United Kingdom
HP11 1NH

Study participating centre
South Camden iCope
Camden and Islington NHS Foundation Trust
The Residence building
St Pancras Hospital
4 St Pancras Way
London
United Kingdom
NW1 0PE

Sponsor information

Organisation
Queen's University Belfast

Sponsor details
Research and Governance Office
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Sponsor type
University/education

Website

http://www.qub.ac.uk

ROR
https://ror.org/00hswnk62

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The CIs will publish the results of the trial in peer-reviewed international journals within 2 years after the completion of the study. In line with open access policies, the main publications will be made open access.

Intention to publish date
30/09/2027

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

HRA research summary			28/06/2023	No	No
Protocol file	version 3.0	25/11/2024	09/01/2025	No	No
Protocol file	version 4	14/01/2025	16/07/2025	No	No