

STAR (Study of Trauma And Recovery): a trial of trauma-focused psychological therapy for psychosis

Submission date 13/12/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 03/08/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/08/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Many people with psychosis (whose symptoms include hearing voices and having unusual beliefs) have had traumatic experiences, both in childhood (such as physical and sexual abuse) and adulthood (such as assaults). About 15% develop the extreme psychological aftermath of having experienced a trauma (Post-Traumatic Stress Disorder; PTSD) as a result, for instance constantly feeling fearful or on edge, having nightmares and 'flashbacks', where the event is relived in the here and now. These problems make psychotic symptoms more intense and long lasting, leading to worse outcomes and increased use of health services. There are effective talking therapies for PTSD, which consist of safely 'reliving' or 'exposure' to the trauma memories with the therapist. This works by allowing the brain to reprocess the trauma so that unwanted distressing memories such as flashbacks and nightmares are reduced. Up to now clinicians have been reluctant to treat people with schizophrenia diagnoses with exposure to the trauma memories, as they fear it might make the psychotic symptoms worse. However, recent studies, including by our group, have shown that such 'Trauma-Focused' therapies can be safe and helpful. National Institute for Health and Care Excellence (NICE) and three recent reviews have recommended that a large randomised controlled trial (RCT) should evaluate this therapy in the NHS, to fill a major gap in treatment for this population.

Aims: We will look at a specific talking therapy to help with PTSD, in people with schizophrenia spectrum diagnoses. We aim to find out whether the therapy reduces PTSD and other symptoms is safe and acceptable, and how much it costs.

Who can participate?

Patients aged 18 years or above with both PTSD and schizophrenia spectrum diagnoses from five NHS mental health trusts.

What does the study involve?

Participants will be allocated randomly to either the Trauma Focused therapy, which is integrated with the standard psychological therapy for psychosis (Cognitive Behaviour Therapy for psychosis; CBTp) + usual treatment, or usual treatment alone. Therapy will last nine months

with a trained therapist. Assessments will include: PTSD symptoms (our main measure); therapy safety and acceptability; service use costs; psychosis symptoms; emotional well-being; suicidal ideation; substance abuse; psychological recovery; and social functioning. These will be assessed four times: before allocation to the two groups; after 4 months (mid-way through therapy); after 9 months (end of therapy, the main time point at which the effectiveness of the new therapy will be compared to the control group); and after 24 months (to check if the effects last). The acceptability of the therapy to participants and therapists will be assessed through qualitative interviews with a subsample of participants (N=35) and therapists (N=5-10). The first 16 months following the start of recruitment will be a pilot study, to make sure recruitment, therapy and assessments are progressing to plan.

What are the possible benefits and risks of participating?

The potential benefits to those receiving the intervention include a reduction in distressing post-traumatic stress, psychosis, and other symptoms.

The research assessments are not designed to have any direct beneficial effect. However, they may have a nonspecific beneficial effect through providing participants with an opportunity to have empathic, warm and normalising conversations about their difficulties and experiences, which may not be discussed in routine clinical care. With participants' permission, a summary of the assessments will be shared with the participant and their care team, which may help inform and shape their usual care.

Where is the study run from?

1. South London and Maudsley NHS Foundation Trust, UK
2. Greater Manchester Mental Health NHS Foundation Trust, UK
3. Northumberland, Tyne and Wear NHS Foundation Trust, UK
4. Sussex Partnership NHS Foundation Trust, UK
5. Oxford Health NHS Foundation Trust, UK

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

February 2020 to February 2025

Who is funding the study?

National Institute for Health Research (NIHR), UK

Who is the main contact?

Dr Emmanuelle Peters

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Contact information

Type(s)

Scientific

Contact name

Dr Emmanuelle Peters

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

275697

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

NIHR 128623, IRAS 275697, CPMS 46008

Study information

Scientific Title

Multisite randomised controlled trial of trauma-focused cognitive behaviour therapy for psychosis (TF-CBTp) to reduce post-traumatic stress disorder (PTSD) symptoms in patients with co-morbid PTSD and psychosis, compared to treatment as usual: the STAR (Study of Trauma And Recovery) trial

Acronym

STAR

Study objectives

Our research question is the following: Is TF-CBTp in addition to TAU clinically and cost-effective in reducing post-traumatic stress symptoms in people with PTSD and psychosis at the end of therapy, compared to TAU alone?

Primary aim: To evaluate the effectiveness of a manualized trauma-focused therapy for psychosis (TF-CBTp) on post-traumatic stress symptoms in people with current PTSD and psychosis at the end of therapy (9m post-randomisation).

Secondary aims:

1. To compare the two groups at 9m post-randomisation (end of therapy) on: (i) percentage of individuals achieving a loss of PTSD diagnosis, and showing clinically significant change; (ii) PTSD

symptom clusters; psychosis symptoms and associated distress; emotional well-being; suicidal ideation; substance use; psychological recovery; social functioning; (iii) cost-effectiveness

2. To determine whether therapy effects endure 24 months post randomisation (15 months post end of therapy), including both clinical and cost-effectiveness
3. To determine the acceptability of TF-CBTp in participants and therapists

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 24/07/2020, Camberwell St Giles Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)207 1048138; camberwellstgiles.rec@hra.nhs.uk), ref: 20/LO/0853

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Post-traumatic stress disorder, schizophrenia, psychosis

Interventions

Treatment arm: Trauma-focused Cognitive Behavioural Therapy for psychosis. TF-CBTp is a manualised therapy integrating standard psychological treatments for PTSD and for psychosis. It will be delivered over a period of 9 months. Approximately 26 weekly or bi-weekly individual, face to face, 60- to 90-min sessions, will be offered in the first 6 months. (Sessions will be face to face where possible, otherwise, they will be conducted remotely, owing to the restrictions imposed by the ongoing COVID-19 pandemic [added 09/10/2020]).

A further 3 monthly sessions will be offered during the next 3 months, following the recommendations made by NICE. They will be done jointly with the care coordinator, to assist with generalisability of treatment effects. Therapists will liaise with the referring teams throughout the delivery of therapy to discuss progress, with the patient's consent, and to share any potential risk to self or others.

Control arm: Treatment as usual in the NHS. Clinical teams will be responsible for the provision of TAU interventions, with no interference from the research team.

Randomisation method: Randomisation will be undertaken using the web-based King's College Clinical Trials Unit (KCTU) randomisation service. Randomisation will be in the ratio 1:1 to the two groups and will be stratified by centre. Randomisation (at the individual level) will be independent and concealed, using dynamically generated permuted blocks of random size (block sizes of 4 or 6).

The randomization system is web-based and allocation is made known to the PI, the Trial Coordinator (in order to monitor adherence to the randomisation algorithm), and the trial therapists only at the point of randomization, by email. The allocation is dynamically generated

and uses randomly varying blocks of sizes not known to the study team so allocation concealment is assured.

The allocation sequence will be generated dynamically by the KCTU. Authorised individuals will be assigned usernames and passwords to log into the system and randomise participants. These individuals may be blind or unblind to group allocation. Randomisation is confirmed via two sets of emails generated by the system. The first set contains the unblinded group allocation and is sent to relevant unblinded individuals in the team. The second set contains no allocation details but is sent to relevant blinded individuals to confirm the participant is enrolled.

The Research Workers will enroll participants, and KCTU will assign participants to the two groups. The therapists will inform the participants to which group they have been randomised to.

COVID -19 related adaptations (added 09/10/2020):

In response to the ongoing COVID-19 pandemic, and in line with the NIHR Restart Framework assessment checklist, a number of adaptations have been made to our study documents and procedures, in order to facilitate remote and face-to-face assessments, and limit participant burden. The documents facilitating these adaptations are as follows:

- A Standard Operating Procedure (SOP) document specifically relating to COVID-19 adaptations. This SOP details the adaptations we will make in order to mitigate risks when holding trial meetings, liaising with clinical teams, recruiting, consenting, assessing, and interviewing participants, delivering the therapeutic intervention, and providing clinical supervision and training to the research team. Facilitating the procedures outlined in the SOP are the documents listed below:
- A staff COVID-19 risk assessment form
- A participant COVID-19 risk assessment form
- A COVID-19 risk assessment guidance document
- A Remote assessment checklist form for research workers
- A remote therapy checklist for therapists
- A COVID-19 specific leaflet for participants, explaining how we will be keeping them safe during their participation in the trial
- A COVID-context questionnaire, designed to help capture the potential impact COVID-19 may have had on participants at each assessment point

Intervention Type

Behavioural

Primary outcome(s)

Current primary outcome measure as of 09/10/2020:

PTSD symptoms in the past month will be assessed on the CAPS-5. The CAPS-5 is a semi-structured interview assessing the severity of symptoms delineated in DSM-5.

The CAPS-5 consists of seven criteria (Criteria A to G). Scores are anchored to an index event, which will be elicited using the mini-TALE and TALE checklists. The index event could be a single trauma experience or multiple, closely related incidents. In this study meeting Criterion A will not be a requirement (i.e., only events including actual or threatened death, serious injury, or sexual violence), as we will include events related to psychosis and its consequences (e.g., involuntary admission or forced restraint), emotional and physical neglect, discrimination and attachment disrupting experiences, as possible index events. PTSD diagnostic status will be determined by an algorithm of minimum scores on specific items from Criteria B to E, and meeting Criteria F and G, according to DSM-5 diagnostic rules.

Once the index event has been ascertained, the severity of symptoms is scored on a 5-point scale ('absent' to 'extreme') on four criteria: (i) Criterion B: Re-experiencing symptoms; (ii) Criterion C: Avoidance symptoms; (iii) Criterion D: Cognitions and mood symptoms; (iv) Criterion E: Arousal and reactivity symptoms. Criteria F and G are scored dichotomously (Yes/No) on whether the duration of the experience is more than 1m, and has caused subjective distress and impairment in functioning, respectively. The total symptom severity score (total of 20 item scores on Criteria B to E) will be the primary outcome

Previous primary outcome measure:

PTSD symptoms in the past month will be assessed on the CAPS-5 at baseline, 4 months (mid-therapy), 9 months (end of therapy; primary endpoint), and 24 months (15 months post-therapy) post-randomisation

Key secondary outcome(s)

Current secondary outcome measures as of 09/10/2020:

At baseline, 4 months (mid-therapy), 9 months (end of therapy; primary endpoint), and 24 months (15 months post-therapy) post-randomisation unless otherwise stated:

1. Symptoms:

1.1. PTSD:

1.1.1. Percentage of people who achieve a loss of their PTSD diagnosis, as determined by the CAPS-5 diagnostic status algorithm

1.1.2. Percentage of people who show clinically significant change in CAPS-5 scores

1.1.3. CAPS-5 individual symptom clusters (severity scores for the individual Criteria B to E)

1.1.4. Self-reported PTSD symptoms and their associated appraisals and responses will be assessed on standardised, commonly used questionnaires:

1.1.4.1. International Trauma Questionnaire

1.1.4.2. Brief Version of the Posttraumatic Cognitions Inventory (PTCI-9)

1.1.4.3. The Dissociative Subtype of PTSD Scale (DSPS)

1.2. Psychosis:

1.2.1. The Psychosis Symptoms Rating Scales (PSYRATS). Additional items to cover hallucinations in non-auditory modalities (i.e., visual, somatic, olfactory and sense of presence), and whether these are experienced at the same or different times (multi-modality), will be included

1.2.2. The Revised Green et al Paranoid Thoughts Scale (GPTS-R)

2. Emotional well-being:

2.1. Depression assessed using the short form of the Depression Anxiety Stress Scales (DASS-21)

2.2. Suicidal ideation will be assessed using the Paykel Suicidal Feelings Scale (PSFS)

2.3. Drug use measured using the Brief Version of the Alcohol, Smoking and Substance Involvement Screening Test (ASSIST)

3. Psychological Recovery: The Short Version of the CHOICE (CHOice of Outcome In Cbt for psychosEs) scale

4. Social and occupational functioning: The Personal and Social Performance Scale (PSP)

5. Health-related quality of life: the EQ-5D-5L

6. Health-related quality of life for users of mental health services: the ReQoL-10

7. Service-use: A modified version of the AD-SUS, designed and successfully applied in psychosis populations

Therapy group only:

8. Acceptability:

A sub-section of the participants will be offered interviews once they have finished therapy to explore acceptability and satisfaction with the therapy. Close attention will be paid to any

emotional distress resulting from memory exposure procedures, in particular potential impact on psychotic symptoms, and whether this was considered unacceptable or unnecessary. The view of those who decided to terminate therapy prematurely will also be gathered, using additional questions about their reasons for doing so and to identify barriers and potential solutions to engagement in therapy.

Therapists will be interviewed once they have completed therapy with two or three participants to obtain feedback about acceptability, and any potential difficulties in delivery.

Experts by experience researchers with lived experience of psychosis will conduct the participant interviews, with appropriate supervision and support, and therapists will be interviewed by Research Workers. It is anticipated that the final patient sample will be representative and include variance on key variables (e.g., intervention engagement, age, gender, ethnicity, clinical presentation). All interview data will be audio-recorded, with participants' permission, and transcribed verbatim for analysis.

Participants' experience of the research assessments will be evaluated following the baseline assessment and at the last assessment (24m) using a brief feedback form, to capture any potential negative and positive aspects.

10. Therapeutic alliance:

Therapeutic alliance between therapists and participants randomised to the intervention arm will be measured using the Working Alliance Inventory – Short Form Revised (WAI-SF-R (81). The therapist and client versions cover three key aspects of alliance: agreement on therapy tasks, agreement on therapy goals and the development of an affective bond (81). Both the self-report participant and therapist versions will be administered.

Previous secondary outcome measures:

At baseline, 4 months (mid-therapy), 9 months (end of therapy; primary endpoint), and 24 months (15 months post-therapy) post-randomisation unless otherwise stated:

1. Symptoms:

1.1. PTSD:

1.1.1. Percentage of people who achieve a loss of their PTSD diagnosis, as determined by the CAPS-5 diagnostic status algorithm

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1.2.2. The Revised Green et al Paranoid Thoughts Scale (GPTS-R)

2. Emotional well-being:

2.1. Depression assessed using the short form of the Depression Anxiety Stress Scales (DASS-21)

2.2. Suicidal ideation will be assessed using the Adult Suicidal Ideation Questionnaire Short Version (ASIQ-SV)

2.3. Drug use measured using the Brief Version of the Alcohol, Smoking and Substance Involvement Screening Test (ASSIST)

3. Psychological Recovery: The Short Version of the CHOICE (CHOice of Outcome In Cbt for psychosEs) scale

4. Social and occupational functioning: The Personal and Social Performance Scale (PSP)
5. Health-related quality of life: the EQ-5D-5L
6. Health-related quality of life for users of mental health services: the ReQoL-10
7. Service-use: A modified version of the AD-SUS, designed and successfully applied in psychosis populations
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Participants' experience of the research assessments will be evaluated following the baseline assessment and at the last assessment (24m) using a brief feedback form, to capture any potential negative and positive aspects.

Completion date

28/02/2025

Eligibility

Key inclusion criteria

Current inclusion criteria as of 12/10/2020:

1. Presence of SSD (F20-29 diagnoses; International Statistical Classification of Diseases and Related Health Problems, 10th Edition; (ICD-10) from clinical notes review, if necessary supplemented by information from the care team
2. Scoring 2 or above ('moderate' intensity) on the intensity of distress item of the Delusions and /or Hallucinations Psychosis Symptom Rating Scales (PSYRATS), adapted to include hallucinations in all modalities
3. Reporting past trauma(s), occurring at least 1 month prior to assessment, including those related to psychotic breakdown or its treatment, assessed using the TALE Checklist
4. Reporting still being currently affected by at least one traumatic event, assessed using the mini-TALE and TALE Checklists
5. Scoring 2 or above ('moderately') on one of the five re-experiencing items from the PCL-5
6. Meet DSM-5 PTSD diagnostic criteria, assessed using the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5), which includes the criteria of 1m stability of symptoms and demonstrable link between the index trauma event(s) and presenting symptoms
7. Both individuals on antipsychotic treatment, and those who decline to take medication, will be included, as long as no medication changes have occurred in the previous 3 months (i.e., having started or stopped antipsychotic medication, or a switch to or from clozapine)
8. Aged 18 years and above
9. Able and willing to engage in psychological therapy and consent to study procedures

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3. Reporting past trauma(s), occurring at least 1 month prior to assessment, including those related to psychotic breakdown or its treatment, assessed using the TALE Checklist
4. Scoring 2 or above ('moderately') on one of the five re-experiencing items from the PCL-5
5. Meet DSM-5 PTSD diagnostic criteria, assessed using the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5), which includes the criteria of 1m stability of symptoms and demonstrable link between the index trauma event(s) and presenting symptoms
6. Both individuals on antipsychotic treatment, and those who decline to take medication, will be included, as long as no medication changes have occurred in the previous 3 months (i.e., having started or stopped antipsychotic medication, or a switch to or from clozapine)
7. Aged 18 years and above
8. Able and willing to engage in psychological therapy and consent to study procedures

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

305

Key exclusion criteria

1. Current, primary diagnosis of substance use disorder
2. Organic factors implicated in the primary aetiology of psychosis and/or PTSD
3. Current (or in previous 3 months) engagement in trauma-focused therapy*
4. Insufficient English to provide informed consent or complete assessments without the help of an interpreter
5. Currently experiencing an acute mental health crisis

*(i.e., any therapy that focuses on reprocessing trauma memories; therapies such as CBTp would be operationalised as 'trauma-informed' rather than 'trauma-focused', since they may include past traumatic experiences in the developmental formulation, but would not include memory work) (added 23/11/2020)

Date of first enrolment

12/10/2020

Date of final enrolment

30/04/2023

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

South London and Maudsley NHS Foundation Trust

16 De Crespigny Park

Camberwell

London

United Kingdom

SE5 8AF

Study participating centre

Greater Manchester Mental Health NHS Foundation Trust

Bury New Rd

Prestwich

Manchester

United Kingdom

M25 3BL

Study participating centre

Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust

Jubilee Rd

Newcastle upon Tyne

United Kingdom

NE3 3XT

Study participating centre

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Swandean
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BN13 3EP

Study participating centre
Warneford Hospital
Oxford Health NHS Foundation Trust
Warneford Lane
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OX3 7JX

Sponsor information

Organisation
South London and Maudsley NHS Foundation Trust

ROR
<https://ror.org/015803449>

Organisation
King's College London

Funder(s)

Funder type
Government

Funder Name
National Institute for Health 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

Individual participant data (IPD) sharing plan

Anonymised datasets generated during and/or analysed during the current study will be available upon request post-publication of the trial results from the Principal Investigator Dr Emmanuelle Peters (emmanuelle.peters@kcl.ac.uk), following a review of the appropriateness of the request by the trial team.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	Participant information sheet	23/05/2022	24/05/2022	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet		11/11/2025	11/11/2025	No	Yes
Protocol file	version 3.05	22/03/2024	12/08/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes