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Seeking Safety feasibility trial

Submission date	Recruitment status	[X] Prospectively registered
12/06/2026	Not yet recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/06/2026	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
18/06/2026	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Many people suffering from severe stress after a traumatic experience try to cope by using alcohol, drugs, or engaging in other risky behaviours which may affect their mental health. To be accepted onto a waiting list for treatment, such as talking therapy, people need to have stopped mis-using alcohol and drugs. Due to their traumatic past, some people feel unable to do this, leaving them unable to make progress towards recovery.

There is a lack of effective treatments for people with combined problems of complex post-traumatic stress disorder and substance use. However, a group programme - Seeking Safety - has been developed in the United States, where it has been effective in tackling trauma and substance use. In the UK, it has been piloted in the NHS with some promising outcomes, but more research is needed especially around the longer-term coping skills which Seeking Safety may provide.

Who can participate?
We are looking for participants who:
• Are over 18 years old
• Have experienced complex trauma
• Are receiving care & support from a community mental health team or are on a waiting list for psychological therapies within South West Yorkshire Partnership Teaching NHS Foundation Trust
• Are able to provide informed consent
• Are willing and able to attend a Seeking Safety group
• Do not experience recurrent episodes of psychosis
• Do not have a severe cognitive impairment
• Are not currently already receiving another psychological therapy for CPTSD or inpatient care
• Do not pose a risk to other people in a group setting

*Individual eligibility will be reviewed by the research team before participants are enrolled in the study.

What does the study involve?
Participants will attend the Seeking Safety group programme which is made up of 20 weekly group sessions.
Participants will be randomly chosen to start the Seeking Safety sessions either within the next 6

months or within the next 18 months.
Participants will complete three online questionnaires – at the beginning of the study, six months later and six months after that. They will receive £30 vouchers for each questionnaire complete.

What are the possible benefits and risks of participating?
There are no known benefits to taking part in this study. We also do not know whether Seeking Safety group sessions help people with complex trauma to feel more supported. However, it is possible that this way of supporting people with complex trauma is acceptable, providing people with better support as well as helping reduce the impact of complex trauma on daily life. You will not receive any financial gain from the data being shared with other researchers.

As this study only involves attending Seeking Safety groups sessions and the completion of routine questionnaires, the risk of harm occurring is minimal. However, being asked to provide regular information about yourself may cause some distress. Should this occur, we will provide additional emotional support where required.

Taking part in this study will involve attending up to 20 weekly sessions. You will complete a questionnaire before being randomly allocated to a group, which will be repeated six months later and then again after a further six months. Some people may feel that collecting all this information or attending Seeking Safety group sessions is too time consuming and is not helpful in terms of support, which will be important for us to understand.

Where is the study run from?
The study is run within the South West Yorkshire Partnership Teaching NHS Foundation Trust's Community Mental Health Teams and psychological therapies waiting lists. More specifically, we are running the study within the Barnsley and Kirklees areas.

When is the study starting and how long is it expected to run for?
The study is aiming to start recruitment of new participants in July 2026 with participant recruitment continuing until end of December 2026.

Who is funding the study?
The study is funded by the National Institute of Health and Care Research (NIHR) Research for Patient Benefit Programme

Who is the main contact?
Please contact the study Trial Manager, Kasia Malczuk by email on research@swyt.nhs.uk or by telephone on 01924 316 289

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Additional identifiers

Central Portfolio Management System (CPMS)
73589

National Institute for Health and Care Research (NIHR)
208168

Study information

Scientific Title
Seeking Safety group intervention for complex post-traumatic stress disorder: a feasibility randomised controlled trial

Study objectives
1. Assess how many people meet the inclusion criteria and accept the invitation to participate in the study (recruitment rate)
2. Determine whether it is acceptable to randomise participants to Seeking Safety groups
3. Determine retention rates at follow-up
4. Determine fidelity and adherence to the Seeking Safety intervention protocol, including number of sessions attended and its relation to outcome
5. Assess the acceptability and feasibility of the measures of outcome, resource use and cost for a definitive trial
6. Investigate the extent of clustering of outcome data from published trials, to assist calculation of the sample size for a full-scale trial
7. Assess participants' experience of Seeking Safety, including experience of single or mixed sex groups and individual sessions; session topics; and factors influencing decisions to (not) continue

with the groups
8. Assess healthcare staff experience of delivering Seeking Safety or supporting individuals accessing it, including their knowledge, training and education needs in relation to Seeking Safety
9. Assess how long participants in the control group are prepared to wait for the intervention
10. Produce a protocol for a definitive trial and economic evaluation

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 02/06/2026, South Central - Oxford C Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; no telephone number provided; oxfordc.rec@hra.nhs.uk), ref: 26/SC/0121

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Complex post-traumatic stress disorder (CPTSD)

Interventions
This is a feasibility trial of Seeking Safety. The objective is to test processes and gather information for the planning of a definitive randomised controlled trial (RCT) to evaluate Seeking Safety for people with complex post-traumatic stress disorder (CPTSD).

We will recruit 56 people with CPTSD to participate in the study in two sites within one mental health NHS trust. We will invite people who meet the inclusion criteria from waiting lists for psychological therapy or on community mental health team (CMHT) caseloads to participate in the study. Each participant must give informed consent to participate.

When minimum numbers have been recruited (please see below), we will ask the participants to complete baseline measures of PTSD symptoms, substance use, mental wellbeing, social functioning, quality of life, service use and a demographic schedule. These measures will be completed via an online questionnaire or, if they are unable to do so, via an interview with the Trial Manager in person, on the telephone or on MS Teams.

We will then randomise participants to either the intervention group or control group. The intervention group will be invited to attend up to 20 sessions of a Seeking Safety group over a 6-month period. In site 1 the group will be held online, and in site 2 the group will be held in person, though there will be an option for women in site 2 to attend an online group for women only to address any concerns about being in a room with men.

In site 1, randomisation will occur when a minimum of 16 participants have been recruited and have completed their baseline questionnaire. In site 2, randomisation will occur when a minimum

of 12 participants have been recruited for each group. However, recruitment will continue until a total of 24 participants have been recruited in site 1 and 32 in site 2.

The control group will continue to receive CMHT care and support, or their place on a waiting list for psychological therapy will not be affected in any way. They will receive Seeking Safety on completion of the study.

At the end of the Seeking Safety groups, 6 months after baseline measurements, participants will be asked to complete the same outcome measures as they did at the beginning, with the addition of a measure of life events that occurred in the previous 6 months.

A final follow-up point for participants will come 6 months after the end of the Seeking Safety groups, when participants will be asked to complete the outcome measures for a final time. Data will be assessed for completeness and analysed for indicative change over time.

We will also conduct semi-structured interviews with participants and Seeking Safety group facilitators to help determine the acceptability and feasibility of the trial design. Up to 20 participants will be interviewed in the follow-up period, after the intervention has been delivered, to explore experiences of Seeking Safety, its impact on their lives, positive and negative aspects of the groups, mode of delivery and which topics they found most useful. We will also explore the acceptability of the trial processes, including randomisation and data collection for both study arms.

Seeking Safety group facilitators will be interviewed about the delivery of Seeking Safety, the value of the training and supervision, and the acceptability, strengths and weaknesses of the intervention. In addition, we will use a brief online survey to explore the wider impact of Seeking Safety in participating CMHTs. All qualitative data will be anonymised, transcribed and then coded using qualitative analysis software.

Intervention Type
Other

Primary outcome(s)
1. Number of eligible people who consent to participate measured using Screening Log, study specific records and consent records at Screening/Pre-consent & Consent

2. Proportion of consented participants who complete baseline data and are randomised measured using Research data, screening log and randomisation records at Baseline & Randomisation

3. Proportion of participants completing end-of-treatment and follow-up assessments measured using Research data and withdrawal records at End of Treatment (6 months post randomisation), 12 months follow up

4. Proportion of participants completing the intervention (defined as attending at least 6 sessions) measured using Attendance records at Intervention period

5. Acceptability and feasibility of completing outcome measures measured using Qualitative interviews and research data at Interview period between End of Treatment (6 months post randomisation) and 12 Months follow up

6. Participants' experience of Seeking Safety measured using Qualitative interviews at Interview period between End of Treatment (6 months post randomisation) and 12 Months follow up

7. Healthcare staff experience of delivering Seeking Safety measured using Qualitative interviews at Interview period between End of Treatment (6 months post randomisation) and 12 Months follow up

8. Control group tolerance of waiting for Seeking Safety measured using Qualitative interviews at Interview period between End of Treatment (6 months post randomisation) and 12 Months follow up

Key secondary outcome(s)
1. PTSD symptoms measured using Impact of Events Scale – Revised (IES-R), a 22-item self-report measure of subjective distress caused by traumatic events, at baseline, end of treatment (6 months post randomisation) and 12 months follow up
2. Substance use measured using Leeds Dependence Questionnaire (LDQ), a 10-item self-report measure designed to assess dependence on a variety of substances, at baseline, end of treatment (6 months post randomisation) and 12 months follow up
3. Mental wellbeing measured using Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS), a widely used 14-item scale for assessing mental wellbeing in the general population, at baseline, end of treatment (6 months post randomisation) and 12 months follow up
4. Social functioning measured using Work and Social Adjustment Scale (WSAS), a 5-item measure assessing the impact of mental health on day-to-day functioning, at baseline, end of treatment (6 months post randomisation) and 12 months follow up
5. Health-related quality of life measured using EQ-5D-5L, a 5-domain tool with an additional self-rated health assessment, at baseline, end of treatment (6 months post randomisation) and 12 months follow up
6. Capability wellbeing measured using ICEpop CAPability Instrument for Adults (ICECAP-A), a 5-item tool assessing wellbeing and quality of life, at baseline, end of treatment (6 months post randomisation) and 12 months follow up
7. Service use measured using a modified version of the Client Services Receipt Inventory (CSRI), adapted for this study to assess service use, at baseline, end of treatment (6 months post randomisation) and 12 months follow up
8. Life events measured using the List of Threatening Experiences (LTE-Q), a 12-item tool assessing the impact of significant life events, at end of treatment (6 months post randomisation) and 12 months follow up

Completion date
31/05/2028

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Diagnosed with CPTSD or assessed as meeting the ICD-11 criteria
3. Receiving care from a CMHT or on a waiting list for psychological therapy in South West Yorkshire Partnership NHS Foundation Trust
4. Able to provide informed consent
5. Willing and able to attend a Seeking Safety group

Healthy volunteers allowed

No

Age group
Mixed

Lower age limit
18 years

Upper age limit
120 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. People with recurrent episodes of psychosis
2. People with a severe cognitive impairment
3. People currently receiving another psychological therapy for CPTSD or inpatient care
4. People assessed as posing a risk to other people in a group setting

Date of first enrolment
01/07/2026

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
South West Yorkshire Partnership NHS Foundation Trust
Trust Headquarters
Fieldhead Hospital
Ouchthorpe Lane
Wakefield
England
WF1 3SP

Sponsor information

Organisation
South West Yorkshire Partnership NHS Foundation Trust

ROR
https://ror.org/02m7qex15

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

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 0.1	08/05/2026	18/06/2026	No	Yes
Protocol file		23/03/2026	18/06/2026	No	No
Study website			12/06/2026	No	No