University of York
Mental Health
Social Care
Research Centre

NHS
South West
Yorkshire Partnership
NHS Foundation Trust

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

Seeking Safety Feasibility Trial

Protocol v.1, 23rd March 2026

This protocol has regard for the HRA guidance and order of content

RESEARCH REFERENCE NUMBERS

IRAS Number:	357616
ISRCTN Number:	TBC
Sponsor	South West Yorkshire Partnership NHS Foundation Trust
Sponsors Number:	TBC
Funders Number:	NIHR Research for Patient Benefit NIHR208168

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), amended regulations (SI 2006/1928) and any subsequent amendments of the clinical trial regulations, GCP guidelines, the Sponsor's (and any other relevant) SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies and serious breaches of GCP from the trial as planned in this protocol will be explained.

For and on behalf of the Trial Sponsor:

Signature: Date:
.....
......./...../.....

Name (please print):
.....

Position:
.....

Chief Investigator:

Signature: Date:
..../...../.....

Name: (please print):
.....

Statistician:

Signature:
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Name: (please print):
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Position:
.....

KEY TRIAL CONTACTS

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Committees	Trial Steering Committee - TBC

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ii. LIST OF ABBREVIATIONS

Define all unusual or 'technical' terms related to the trial. Add or delete as appropriate to your trial. Maintain alphabetical order for ease of reference.

AE	Adverse Event
AR	Adverse Reaction
CA	Competent Authority
CI	Chief Investigator
CRF	Case Report Form
CRO	Contract Research Organisation
CTA	Clinical Trial Authorisation
CTIMP	Clinical Trial of Investigational Medicinal Product
CTU	Clinical Trials Unit
DMC	Data Monitoring Committee
DSUR	Development Safety Update Report
EC	European Commission
EMEA	European Medicines Agency
EU	European Union
EUCTD	European Clinical Trials Directive
EudraCT	European Clinical Trials Database
EudraVIGILANCE	European database for Pharmacovigilance
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
IB	Investigator Brochure
ICF	Informed Consent Form
ICH	International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use.
IMP	Investigational Medicinal Product
IMPD	Investigational Medicinal Product Dossier
ISF	Investigator Site File (This forms part of the TMF)
ISRCTN	International Standard Randomised Controlled Trials Number
MA	Marketing Authorisation
MHRA	Medicines and Healthcare products Regulatory Agency
MS	Member State
NHS R&D	National Health Service Research & Development

NIMP	Non-Investigational Medicinal Product
PI	Principal Investigator
PIC	Participant Identification Centre
PIS	Participant Information Sheet
QA	Quality Assurance
QC	Quality Control
QP	Qualified Person
RCT	Randomised Control Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SDV	Source Data Verification
SOP	Standard Operating Procedure
SmPC	Summary of Product Characteristics
SSI	Site Specific Information
SUSAR	Suspected Unexpected Serious Adverse Reaction
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee

iii. TRIAL SUMMARY

Trial Title	Seeking Safety group intervention for complex post-traumatic stress disorder: a feasibility randomised controlled trial	
Internal ref. no. (or short title)	Seeking Safety feasibility trial	
Clinical Phase	Feasibility	
Trial Design	Individual 1:1 RCT	
Trial Participants	People aged 18 or over who are diagnosed with complex post-traumatic stress disorder who would consider attending a group intervention	
Planned Sample Size	56	
Treatment duration	6 months	
Follow up duration	6 months	
Planned Trial Period	April 2026 – May 2028	
	Objectives	Outcome Measures
Feasibility	a) Number of eligible people who consent to participate	Screening log (study-specific) records and consent records
	b) Proportion of consented participants who complete baseline data and are randomised	Research data, screening log and randomisation records
	c) Proportion of participants completing end-of-treatment and follow-up assessments	Research data and withdrawal records
	d) Proportion of participants completing the intervention (defined as attending at least 6 sessions)	Attendance records
	e) Acceptability and feasibility of completing outcome measures	Qualitative interviews and research data
	f) Participants' experience of Seeking Safety	Qualitative interviews
	g) Healthcare staff experience of delivering Seeking Safety	Qualitative interviews

	h) Control group tolerance of waiting for Seeking Safety	Qualitative interviews

iv. FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this trial)	**FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN**
NIHR Research for Patient Benefit (NIHR208168) Dr Heather Ford, Programme Manager heather.ford@nihr.ac.uk	**£289,330**

v. ROLE OF TRIAL SPONSOR AND FUNDER

The Sponsor (South West Yorkshire Partnership Foundation NHS Trust) has overall responsibility for the initiation and management of the trial. The Sponsor has responsibility for hosting the trial, recruiting participants, managing the delivery of the intervention and collecting data. The University of York will work in partnership with the Sponsor to deliver the trial. In particular, the University of York has designed the trial, will supervise the trial manager and conduct of the trial, undertake data analysis and interpretation, lead manuscript writing and dissemination of findings.

The funder (NIHR Research for Patient Benefit) will monitor the progress of the trial but will not play any direct role in it.

vi. ROLES AND RESPONSIBILITIES OF TRIAL MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

Trial Management Committees

Trial Steering Committee (TSC)

The TSC will oversee the conduct and safety of the trial, ensuring that milestones are achieved and general scientific probity is maintained. The TSC will monitor progress of the trial, adherence to the protocol and consider new information of relevance to the research question. In the absence of an independent Data Monitoring Committee, the TSC will also oversee the safety and ethics of the trial, reviewing recruitment, primary outcome data completeness and adverse events data. The TSC will include an independent chair (clinician/trialist), independent clinician, an independent lay representative, an independent statistician, the Chief Investigator (CI) and lead Allied Health Professional.

The TSC will be established in conjunction with the Trial Management Group (TMG). Membership, responsibilities and reporting mechanisms of the TSC will be formalised in a TSC charter.

Observers may also attend (including other members of the TMG or members of other professional bodies) at the invitation of the Chair. The TSC will meet for the first time prior to recruitment of the first participant and then at six-month intervals thereafter.

Trial Management Group (TMG)

The TMG will have responsibility for the day-to-day management of the trial and will report to the TSC. The TMG will include the CI, lead allied health professional, Trial Manager, trial statistician, health

economist and other relevant personnel (e.g. clinical colleagues, PPI representatives, Sponsor representative, as required). The TMG will meet monthly throughout the trial to ensure development of study documentation and approvals, monitor progress (including participant recruitment), resolve day-to-day problems as they arise, review the budget, discuss analysis, results, draft reports and dissemination.

Patient and Public Involvement (PPI)

A Lived Experience Advisory Group (LEAG) will be appointed. This will comprise up to eight people with lived experience of CPTSD, including those who have participated in Seeking Safety groups, or their family members / carers. Recruitment of LEAG members will be undertaken by the Research and Development Department in SWYT, who will apply equality and diversity principles in the selection of members to help ensure that the LEAG will be as inclusive and diverse as possible. LEAG members' time will be reimbursed at standard NIHR rates for public contributors. The PPI leads for the trial will bring issues, concerns and feedback from the LEAG to monthly TMG meetings to ensure that the group's discussions are heard in full and acted upon. The impact of the LEAG input into the TMG will be recorded in the meeting minutes.

The LEAG will meet five times during the study, including during study set up, during the recruitment period, during the intervention and before the end of the study. It will advise on interview schedules and topic guides; review recruitment and data collection processes; discuss the progress of the intervention; support the interpretation of the findings; and coproduce outputs including an accessible report.

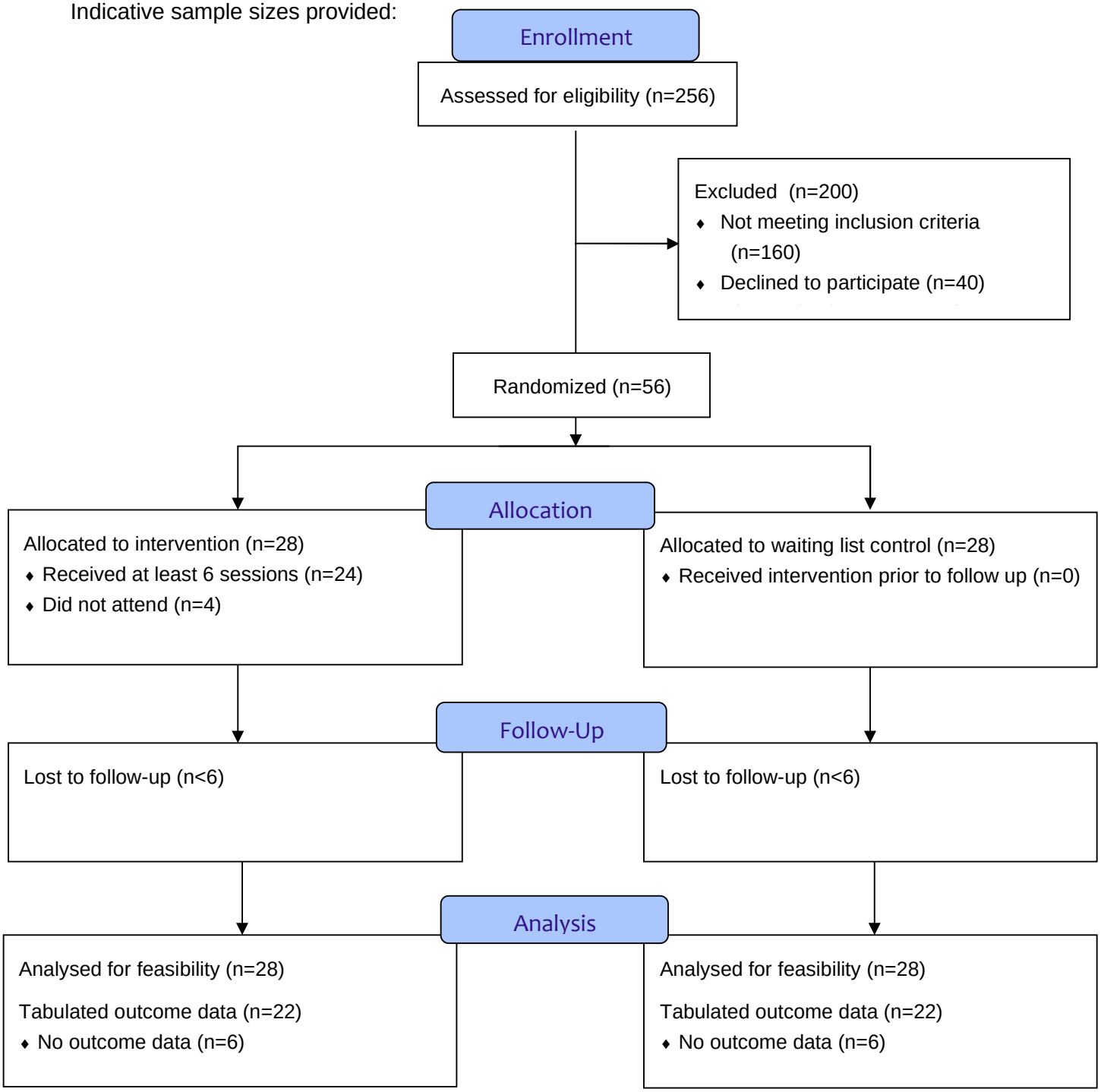
vii. Protocol contributors

The protocol has been developed by the research team and lived experience contributors. This has included inputs from social workers, occupational therapists, psychologists, statisticians and health economists. People with lived experience have informed the development of the protocol through feedback about Seeking Safety and comments about the design of the trial.

viii. KEY WORDS: Feasibility trial; Seeking Safety; complex post-traumatic stress disorder; waiting list

ix. TRIAL FLOW CHART

Indicative sample sizes provided:



1 BACKGROUND

People with complex post-traumatic stress disorder (CPTSD) present to NHS mental health services with acute symptoms of trauma, which they often manage with alcohol, drugs, or other unsafe coping behaviours [1]. Psychological therapy, particularly trauma-focused cognitive behavioural therapy, is the recommended treatment [2]. However, this requires an individual to be psychologically and socially stable so that the process of therapy does not destabilise the person further. People who are unable to achieve this stability independently cannot access psychological therapy to address their trauma but still need care to manage episodes of crisis.

Seeking Safety is a manualized group treatment for people with CPTSD and drug and/or alcohol use, which was developed in the United States and is used internationally (it has been translated into 16 languages) [3]. It draws upon cognitive behavioural therapy and concurrently addresses CPTSD and substance use in 25 educational sessions of coping and mental life skills building. Embedded in the treatment is an understanding that there are multiple other behaviours which serve a similar numbing or blocking-out function, and so the treatment can be used effectively to help people with a variety of unsafe coping behaviours, such as self-isolating, gambling, unsafe sex, and overspending when they co-exist with a trauma history [3]. Seeking Safety helps people to achieve stabilisation by creating a safe environment for them within a group; building skills and strategies to cope with trauma and coexisting mental health and unsafe behaviours; and fostering emotional stability and healthier choices.

CPTSD is a new diagnosis in ICD-11, but it is estimated that the one-month prevalence is between 1% and 8% in the general population [1] and the lifetime prevalence in the UK is 13% [4]. This is much higher in at-risk populations such as refugees, with estimates ranging from 16-38% [5]. Many people remain undiagnosed or untreated, though may attract other diagnoses that further delay the treatment of underlying trauma [6]. Although limited data exists on the health, social care and wider societal costs of CPTSD, the direct and indirect costs of PTSD are known to be substantial [7].

Up to 50% of caseloads of mental health practitioners, social workers, psychological and allied health professionals (i.e. occupational therapists) in community mental health teams (CMHTs) are people who are unable to make progress toward recovery from past trauma because they are unable to achieve required levels of stability [4]. These workload pressures are compounded by the lack of an effective treatment pathway for people with CPTSD and problems of substance misuse. Finding effective and cost-effective interventions to provide stabilisation for people with CPTSD has been highlighted as a research priority by the National Institute for Health and Care Excellence (NICE) [2].

Embedding Seeking Safety as part of normal practice has the potential to deliver cost savings to the NHS through improved mental and physical health outcomes and reduced healthcare utilisation, with benefits to the individuals affected, their carers and families, and wider society. In particular, those who progress from the Seeking Safety group into trauma-focused therapy programmes may need less time in individual therapy as they are already equipped in stabilisation skills. This might reduce pressure on the waiting list for psychological therapy and reduce the workload of CMHT staff. This feasibility study is the first stage in evaluating the benefits of Seeking Safety for patients and the NHS. The anticipated timescale for patient benefit will be approximately six years, should the findings of this study and a full trial be promising.

Evidence of the effectiveness of Seeking Safety, based on two meta-analyses of over a thousand patients, indicates medium to large effects on PTSD and small to medium effects on substance use disorder (SUD), which is consistent with the broader literature that indicates greater difficulty treating SUD [8, 9]. This is particularly notable as Seeking Safety studies have generally included a wider array of patients than classic PTSD treatment trials that typically exclude people with more severe and complex problems [10]. Moreover, classic PTSD treatments such as exposure therapy generally do not outperform SUD-alone treatment in PTSD/SUD samples [11]. However, one review found Seeking

Safety had an effect on SUD only at the end of treatment [12]. Abbreviated versions of Seeking Safety appear as effective as the full version [8].

Evidence for Seeking Safety is predominantly from the United States. We conducted a systematic scoping review of bibliographic databases (PubMed, PsychINFO, Embase, Medline, CINAHL, Cochrane Central Register of Controlled Trials) and found only one small (n=7) study conducted in the UK, which was predominantly qualitative [13], and no RCTs [14]. The review also identified several gaps in the research including the optimal duration of treatment, number of sessions and topics; knowledge, training and education needs of healthcare professionals providing Seeking Safety; and whether single sex groups or individual sessions are best [14]. These questions will be explored in this study.

Our pilot in SWYT found that up to 75% of participants did not need further treatment after the primary intervention and 84% of those who completed treatment had a reduced symptom severity [15]. One participant said: “As the course has progressed, drinking has lost its hold on me. It does not figure in my life. It is almost like the glass has been emptied of alcohol and is now full…. Crammed and stuffed full of life.” This pilot was based on clinician administered outcome measures and patient feedback and, although it provided valuable data about the potential outcomes of Seeking Safety, it was not sufficiently rigorous to inform NICE guidelines.

A search of the ISRCTN registry found that no trial of Seeking Safety has, or is being conducted, in an NHS setting, nor has any trial answered the questions posed by our proposal.

2 RATIONALE

The aim of this study is to investigate whether it is feasible and acceptable to undertake an RCT of the effectiveness and cost-effectiveness of Seeking Safety as a treatment to improve mental health outcomes for individuals with CPTSD compared with a wait-list control.

The primary objectives are to:

- Assess how many people meet the inclusion criteria and accept the invitation to participate in the study (recruitment rate)
- Determine whether it is acceptable to randomise participants to Seeking Safety groups
- Determine retention rates at follow-up
- Determine fidelity and adherence to the Seeking Safety intervention protocol, including number of sessions attended and its relation to outcome
- Assess the acceptability and feasibility of the measures of outcome, resource use and cost for a definitive trial
- Assess participants' experience of Seeking Safety, including experience of single sex groups and individual sessions; session topics; and factors influencing decisions to (not) continue with the groups
- 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
- Assess how long participants in the control group are prepared to wait for the intervention

2.1 Assessment and management of risk

The potential risks of Seeking Safety and the mitigations are summarised in table 1.

Table 1 Risks and mitigations

Risk	Mitigation
Re-traumatization, increased anxiety and stress Discussing trauma can trigger intense emotions and feelings, potentially leading to re-traumatization, especially for people with complex trauma histories. The process of exploring difficult experiences can heighten anxiety and stress levels, particularly if coping mechanisms are not yet well-established.	The groups will be facilitated by experienced mental health professionals with specific training in Seeking Safety. They will introduce trauma-related topics gradually and in a way that respects individual boundaries to minimise any potential re-traumatization, anxiety and stress. Seeking Safety teaches coping skills, which can empower participants to manage difficult emotions and experiences more effectively.
Negative group effects Sharing personal trauma stories in a group setting can be a negative experience if the group is not properly facilitated. Some people may feel isolated or judged within the group, hindering their ability to engage and benefit from the therapy.	The skilled group facilitators will place a strong emphasis on safety, confidentiality, and non-judgment with the groups. They will carefully manage group dynamics to ensure everyone is included and works together effectively within the group.
Unsafe behaviours	The group facilitators will offer individual support and guidance to participants to address specific

In some cases, individuals struggling with substance use or trauma-related symptoms may engage in unsafe behaviours within the group or outside of the group.	needs or behaviours which may emerge during the group. They will encourage open communication and feedback to help identify and address potential issues within the group.
<u>Disclosure of risk</u> There may be a risk of participants disclosing a risk to another child or adult in Seeking Safety group sessions or in research interviews.	A risk protocol has been developed which advises group facilitators and researchers about actions to take should risks to others be disclosed in the course of the project. Appropriate training will be provided to group facilitators and researchers in assessing risk and using the protocol.

This trial is categorised as:

- Type A = No higher than the risk of standard medical care

3 OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

The aim of this study is to investigate whether it is feasible and acceptable to undertake an RCT of the effectiveness and cost-effectiveness of Seeking Safety as a treatment to improve mental health outcomes for individuals with CPTSD compared with a wait-list control.

3.1 Objectives

The objectives of this feasibility study are to:

- Assess how many people meet the inclusion criteria and accept the invitation to participate in the study (recruitment rate)
- Determine whether it is acceptable to randomise participants to Seeking Safety groups
- Determine retention rates at follow-up
- Determine fidelity and adherence to the Seeking Safety intervention protocol, including number of sessions attended and its relation to outcome
- Assess the acceptability and feasibility of the measures of outcome, resource use and cost for a definitive trial
- Investigate the extent of clustering of outcome data from published trials, to assist calculation of the sample size for a full-scale trial
- 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
- 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
- Assess how long participants in the control group are prepared to wait for the intervention
- Produce a protocol for a definitive trial and economic evaluation

3.2 Outcome measures/endpoints

The feasibility endpoints / outcomes are summarised in table 2.

Table 2 Summary of feasibility endpoints / outcomes and measures / tools

Feasibility outcome	Measure / tool
a) Number of eligible people who consent to participate	Screening log (study-specific) records and consent records
b) Proportion of consented participants who complete baseline data and are randomised	Research data, screening log and randomisation records
c) Proportion of participants completing end-of-treatment and follow-up assessments	Research data and withdrawal records
d) Proportion of participants completing the intervention (defined as attending at least 6 sessions)	Attendance records

e) Acceptability and feasibility of completing outcome measures	Qualitative interviews and research data
f) Investigate clustering of outcome data	Review data from published trials
g) Participants' experience of Seeking Safety	Qualitative interviews
h) Healthcare staff experience of delivering Seeking Safety	Qualitative interviews
i) Control group tolerance of waiting for Seeking Safety	Qualitative interviews

3.3 Primary endpoint/outcome

Participant outcomes will be measured at baseline, end of the intervention and 6-months post-treatment. Clinical endpoints / outcomes are summarised in table 3. This data is collected to understand feasibility of data collection to inform a definitive trial and not conduct hypothesis testing.

Table 3 Participant endpoints / outcomes

Outcomes	Measure
PTSD symptoms	Impact of Events Scale – Revised (IES-R) [16] A 22-item self-report measure of subjective distress caused by traumatic events.
Substance use	Leeds Dependence Questionnaire (LDQ) [17] A 10-item self-report measure designed to measure dependence upon a variety of substances.
Mental wellbeing	Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) [18] A widely-used 14-item scale to measure mental wellbeing in the general population.
Social functioning	Work and Social Adjustment Scale (WSAS) [19] A 5-item measure which assesses impact of mental health on a person's day-to-day lives.
Health-related quality of life	EQ-5D-5L [20] A 5-domain tool with additional self-rated health assessment.
Capability wellbeing	ICEpop CAPability Instrument for Adults (ICECAP-A) [21] A 5-item tool to assess wellbeing and quality of life.
Service use	Modified version of Client Services Receipt Inventory (CSRI) [22] This tool will be specifically adapted for this study to measure service use.

Life events (assessed at end of treatment and follow-up only)	List of Threatening Experiences (LTE-Q) [23] This 12-item tool will be used to account for the potential impact of significant life events on outcomes.

4 TRIAL DESIGN

4.1 Summary of trial design and setting

The design of the feasibility study is a parallel group, wait-list, feasibility RCT, economic scoping and nested qualitative study. The trial will take place in two sites within SWYT.

4.2 Project timetable and duration of participation

The start date for the trial is 1st April 2026 and the study duration is expected to be 26 months to 31st May 2028.

Fifty-six participants will be recruited and randomised (enrolled) over a 6-month period. For all participants, individual trial participation will be from the time of written informed consent until 6 months (+/- 2-weeks) post-intervention. A sub-set of up to 20 participants and 4 staff will be selected through purposive sampling to undertake a detailed telephone or video call interview for the nested qualitative study. This will be undertaken upon completion of the treatment phase (6 months post-randomisation) and before the 6-month follow-up timepoint.

4.3 Blinding and strategies for minimising bias

This is a small feasibility study with data collection being managed by a single researcher (trial manager). No blinding of the trial manager is proposed, though the statistician who will conduct the data analysis will be blinded. For a full trial, we will aim to blind researchers when collecting outcome data and the statistician completing the analysis.

To reduce selection bias, broad inclusion criteria will be applied. Given this is an RCT it is anticipated that intervention and control groups will have similar baseline demographics.

5 PARTICIPANT ELIGIBILITY CRITERIA

The trial population is people with CPTSD on a CMHT caseload or waiting list for psychological therapy in participating localities in SWYT.

5.1 Inclusion criteria

Potential participants must satisfy the following criteria to be enrolled in this study:

- Aged 18 or over
- Diagnosed with CPTSD or assessed as meeting the ICD-11 criteria
- Receiving care from a CMHT or on a waiting list for psychological therapy in SWYT
- Able to provide informed consent
- Willing and able to attend a Seeking Safety group

5.2 Exclusion criteria

Potential participants who meet the following criteria will be excluded from participation:

- People with recurrent episodes of psychosis
- People with a severe cognitive impairment
- People currently receiving another psychological therapy for CPTSD or inpatient care
- People assessed as posing a risk to other people in a group setting

People with a substance use disorder, suicidal or violence ideation or other maladaptive behaviours will not be excluded, as this is a common presentation or co-morbidity with CPTSD.

5.3 Co-enrolment to other studies

The CI will ensure appropriate co-enrolment agreements are in place for all studies/trials where similar inclusion criteria are applied. These agreements will consider participant burden. In the event of overlapping randomised interventions, it will be at the discretion of the local Principal Investigators (PIs) as to which trial a carer/service user should be approached for potential participation. It will not be possible for participants in this trial to be enrolled on another trial for a therapy for CPTSD, as per our exclusion criteria above.

6 TRIAL PROCEDURES

6.1 Recruitment

6.1.1 Participant identification

Clinical Studies Officers within SWYT will work with healthcare staff to screen waiting lists for psychological therapy and CMHT caseloads in the two sites for people who meet the inclusion criteria. They will access patient records in order to check that potential participants meet the inclusion criteria. They will approach those who appear to meet the inclusion criteria to ascertain their willingness to participate in a Seeking Safety group and to participate in the trial.

In addition, we will identify potential participants through research ambassadors and the research involvement group within SWYT who will share leaflets about the study. Leaflets and the SWYT website will include QR codes so that potential participants (who are already on a caseload of a participating team within SWYT) can access the study information sheet and self-refer to the research team if they consider themselves to be eligible.

6.1.2 Screening

Patient records will be screened to ascertain age (18 or over); whether they appear to meet the criteria for a diagnosis of CPTSD; and whether the person is receiving care from a CMHT or on a waiting list for psychological therapy in SWYT. If any clarification about the diagnosis is required, Clinical Studies Officers will ask the clinical team involved to provide confirmation that the potential participant is likely to meet the ICD-11 criteria for CPTSD. If a formal diagnosis has not been made, a Psychological Professional or a Psychiatrist will be asked to provide an opinion as part of the multi-disciplinary team.

Healthcare staff will approach those who appear to meet the inclusion criteria and provide written information sheets about the study in routine appointments, or by e-mail following telephone contact. They will also determine whether the person is agreeable to being contacted by a member of the research team. If the person expresses an interest in the study, they will be asked to provide verbal consent to be contacted by The Trial Manager and their preferred method of contact.

The Trial Manager will arrange a time to conduct telephone interviews with those who are interested in participating in the study to assess their eligibility, including their capacity to give consent to participate and their willingness to attend a Seeking Safety group.

Site staff will complete a trial-specific screening log, which will be developed in line with the SEAR (Screened, Eligible, Approached, Randomised) framework [24]. This framework will enable us to record the flow of potential participants through the recruitment process, in line with recommended Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines [25, 26]. For those who are screened but not eligible to participate, anonymized information about the reasons why they are not eligible will be collated, in addition to their age, gender and ethnicity.

6.1.3 Payment

No payments will be made to participants, though £30 shopping vouchers will be provided for each questionnaire or interview completed.

6.2 Consent

The Principal Investigator (PI) delegates responsibility for the taking of informed consent of participants to the Trial Manager. This person will be duly authorised, trained and competent to undertake this according to the ethically approved protocol, principles of Good Clinical Practice (GCP) and Declaration of Helsinki.

Informed consent must be obtained prior to the participant entering the trial and completing baseline measures. The right of a participant to refuse participation without giving reasons will be respected.

The participant will remain free to withdraw at any time from the trial without giving reasons and without prejudicing their treatment. The information sheet provides a contact point where participants may obtain further information about the trial. Data collected up to the point of withdrawal will only be used after withdrawal if the participant has consented for this on the consent form. If a participant is required to re-consent, or new information is required to be provided to a participant, the PI will ensure this is done in a timely manner.

The PI takes responsibility for ensuring that all vulnerable participants are protected and participate voluntarily in an environment free from coercion or undue influence

Participant information sheets will be translated into other languages as required. The Trial Manager will take necessary steps to ensure that participants receive the support they require to read and understand the information about the trial. They will discuss the information sheet with potential participants, including the nature and objectives of the trial and possible risks associated with their participation. The information sheet and consent form will be approved by the HRA Research Ethics Committee and will be in compliance with GCP, local regulatory requirements and legal requirements. Potential participants will have the opportunity to ask questions.

For consent to be ethical and valid in law, participants must be capable of giving consent for themselves. A capable person will:

- understand the purpose and nature of the research
- understand what the research involves, its benefits (or lack of benefits), risks and burdens
- understand the alternatives to taking part
- be able to retain the information long enough to make an effective decision.
- be able to make a free choice
- be capable of making this particular decision at the time it needs to be made (though their capacity may fluctuate, and they may be capable of making some decisions but not others depending on their complexity)
- where participants are capable of consenting for themselves but are particularly susceptible to coercion, it is important to explain how their interests will be protected

Participants must be able to give consent themselves in order to participate in this trial. If a participant is able to give consent for participation, but later becomes incapacitated, their data will be used if the participant has consented for this on the consent form. If the participant does not withdraw from the trial, the Trial Manager will re-assess their capacity to give consent at subsequent follow-up data collection points prior to administering research schedules. In all such cases the original consent given endures the loss of capacity, providing that the trial has not significantly altered (there may be clinical justification under such circumstances for cessation of attendance at Seeking Safety groups while data collection for follow-up purposes continues).

We will collect data on age, sex, ethnicity, sexual orientation and socioeconomic status of participants when they give their consent to participate in the trial. This will be monitored by the research team each month during the recruitment phase to assess the extent to which the sample is representative of the target population of people with CPTSD in SWYT. If particular groups are under-represented in the sample, we will discuss this with the LEAG to seek their guidance on how best to adjust our recruitment methods as appropriate. This may include sending study information to under-represented groups via email, for example. We will translate study recruitment materials for potential participants who cannot read in English to ensure that our sample is as inclusive as possible.

6.3 The randomisation scheme

Delivery of the intervention will be in mixed sex groups. These groups will be held online in one site and in-person in the other site to evaluate the feasibility of different modes of delivery. In the site with in-person delivery, there will also be an option for a women-only online group. Therefore, the target sample sizes and randomisation scheme will be different in each site.

In the site with online delivery to a mixed sex group, our target sample size will be 24. However, we will undertake the first randomisation when we have consented and received complete baseline data from 16 participants who are available to attend the intervention, as this should provide a minimum group size of 8. Collection of baseline data will commence when this minimum number has been reached. If participants do not complete baseline data, they will not be randomised and recruitment of additional participants will continue until a minimum of 16 have provided baseline data. It should be made clear to participants that there may be a delay in receiving an outcome of the randomisation due to this criteria and that this could take up to 6 months in total. After the first randomisation, we will continue recruitment until our target sample of 24 is achieved. The remaining participants will be randomised when they have been consented and provided their baseline data.

In the site with in-person delivery to a mixed sex group, our target sample size will be 32. However, we will undertake the first randomisation when we have consented and received complete baseline data from 12 participants who are available to attend the intervention in-person, or 12 who have requested the women-only online group. Collection of baseline data will commence when this minimum number has been reached. If participants do not complete baseline data, they will not be randomised and recruitment of additional participants will continue until a minimum of 12 have provided baseline data. It should be made clear to participants that there may be a delay in receiving an outcome of the randomisation due to this criteria and that this could take up to 6 months in total. After the first randomisation, we will continue recruitment until our target sample of 32 is achieved. The remaining participants will be randomised when they have been consented and provided their baseline data.

We will block randomise participants, half to the intervention group and half to the control group. Allocation will be withheld from the clinicians and participants until all baseline data has been collected. We will carry out this process at least 4 times with the hope of creating intervention groups with at least 8 participants, and a similar number of control participants.

As we will run through all the Seeking Safety topics twice, participants who join part of the way through the sequence of topics will have an opportunity to attend sessions which cover topics they will have missed.

6.3.1 Method of implementing the randomisation/allocation sequence

An online randomisation system will be used, with the randomisation sequence being generated by the company “Sealed EnvelopeTM” [27]. Randomisation will be undertaken by the trial statistician within the central trial team who is blinded to the participant’s identities using unique participant identifiers. Participants will be randomised simultaneously once recruitment and baseline data collection is complete for that site. This will be co-ordinated by the Trial Manager.

To randomise a participant, the trial statistician will sign into the online randomisation system and enter brief participant details (e.g. unique study P.I.D. number, study site, sex, date of birth and date of informed consent). Once the online randomisation process is complete, the computer screen will indicate which participants have been allocated to the intervention group and which to the control group. “Sealed EnvelopeTM” will automatically send an email to relevant users that have ‘notifications enabled’ confirming the randomisation. Confirmation of randomisation outcomes will be provided to site staff by the Trial Manager. Appropriate site staff will place a record (electronic or print out) of the allocation generated by the randomisation website in the site file.

Once a participant has been randomised, intervention delivery can proceed. The Trial Manager should proceed to complete and send a study approved letter to the participant. A copy of this letter should also be filed in the site file.

6.4 Blinding

This is a small feasibility trial with only one research staff (the Trial Manager) involved in data collection processes. No blinding of the Trial Manager is proposed for this study as this is not feasible. However, they will undertake the study procedures identically in the control and intervention groups. Instead, the statistician who will conduct the data analysis will be blinded. For a full trial, we will aim to blind researchers when collecting outcome data and the statistician completing the analysis.

6.5 Baseline data collection

Participants will self-complete an online questionnaire using Qualtrics (Provo, Utah, USA) to provide baseline data. Qualtrics provides secure password-protected cloud data storage and is licenced for University of York staff to use. Qualtrics is an accessible data collection tool which can be used on mobile phones, laptops and other mobile devices. If participants are unable to access it, or self-complete the questionnaire, they will be offered an interview with the Trial Manager in person, on the telephone or on MS Teams. The Trial Manager will enter their data directly into Qualtrics.

The baseline data collection schedule will include the outcome measures in table 3. In summary, these include at least the following:

- Impact of Events Scale – Revised (IES-R) [16]
- Leeds Dependence Questionnaire (LDQ) [17]
- Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) [18]
- Work and Social Adjustment Scale (WSAS) [19]
- EQ-5D-5L [20]
- ICEpop CAPability Instrument for Adults (ICECAP-A) [21]
- Client Services Receipt Inventory (CSRI) [22]

These outcomes have been judged to be important by healthcare professionals delivering Seeking Safety and people with lived experience who have been consulted in the course of developing this study. The measures are brief, but their feasibility and burden will be assessed during the study.

In addition, at baseline the following demographic data will be collected:

- Contact details
- NHS number
- Demographics, including date of birth and sex
- GP contact details
- Details about usual residence (e.g. own home, residential home)
- Employment status
- Level of education
- Diagnosis or co-morbid conditions (from NHS patient records)

Baseline data collection must be completed prior to randomisation and for participation in the trial. All data collection and participant-related activities are summarised in table 4.

6.6 Intervention period

Clinicians delivering Seeking Safety groups will collect attendance data during the weekly sessions in the intervention group only.

6.7 End of intervention data collection

The intervention comprises 25 topics which will be delivered in up to 20 weekly sessions over a 6-month period. Some sessions will include two topics (which has been demonstrated to be feasible in other evaluations of Seeking Safety) and each session will typically last up to 90 minutes. The sequence of sessions will be repeated once so that participants who are randomised after the first randomisation will be able to attend sessions covering topics they missed. End of intervention data collection will be at 6 months post-randomisation (+/- 2 weeks). This includes 2 weeks set-up prior to the intervention and 2 weeks during the intervention period for holiday breaks. Questionnaires will be sent automatically when a participant enters the data collection window. Research staff will follow-up participants twice who have not responded. The data collection will include the same outcome measures used at baseline with the addition of:

- List of Threatening Experiences (LTE-Q) [23]

6.8 Follow-up data collection

Follow-up data collection will be at six months post end of intervention (12 months post-randomisation +\- 2 weeks)). Questionnaires will be sent automatically when a participant enters the data collection window. Research staff will follow-up participants *twice* who have not responded. The data collection will include the same measure used at end of intervention.

Table 4 Trial assessments and key participant-related procedures

Data collection timepoint (→)	**Pre-randomisation**			**Point of randomisation**	**Post-randomisation**					
Key data capture (measures) / trial procedures (↓)	**Identification / Screening**	**Consent**	**Baseline**		**Up to 20 weekly sessions**				**6 months**	**12 months**
Screening	●									
Eligibility assessment	●									
Consent to join trial		●								
Impact of Events Scale – Revised (IES-R)			●						●	●
Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS)			●						●	●
Leeds Dependence Questionnaire (LDQ)			●						●	●
Work and Social Adjustment Scale (WSAS)			●						●	●
ICEpop CAPability measure for Adults (ICECAP-A)			●						●	●
Quality of life / utility (EQ-5D-5L)			●						●	●
Service use (CSRI)			●						●	●
Randomisation				●						
List of Threatening Experiences (LTE-Q)									●	●
Seeking Safety sessions [A]					→	→	→	→		
Qualitative interviews [B]	→								→	
Staff survey [C]									→	

***Key**: ● data capture / outcome measures; completion methods may vary depending on participant preferences. [A] Intervention arm only – Seeking Safety facilitators will complete attendance records after each session. There will be up to 20 weekly sessions across 6 months. [B] Months 6-12 Decline/ withdrawal Feedback end of treatment qualitative interviews (see Section 9).*

6.9 Qualitative assessments

The embedded qualitative study will assist in determining the acceptability and feasibility of the trial design and the intervention and will help to optimise recruitment in the main trial. Semi-structured interviews will be conducted with recruited participants, those who decline participation or later withdraw from the study, and staff involved in recruitment and delivery of the intervention.

6.9.1 Participants

We will explore intervention group participants' experiences of Seeking Safety and the factors influencing their decisions whether to attend the group sessions. We will also explore with them their experiences of online or in-person delivery; single or mixed sex groups; individual sessions; and which session topics they found most useful, including their perceived outcomes of attending Seeking Safety sessions. In addition, we will explore the acceptability of the trial processes including randomisation and data collection for both study arms after the delivery of the intervention, and the experience of waiting for the intervention in the control group.

We anticipate a sample size of 20 participants (approximately twelve from the intervention group and eight from the control group) will be sufficient to address our feasibility and acceptability questions.

These interviews will be conducted following post-intervention data collection and during the follow-up period.

6.9.2 NHS Staff

Those delivering the intervention will be interviewed at the end of the intervention period, with interviews focussing on ease of delivery, the value of training and supervision, as well as 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. We will use open questions to ask clinicians, service managers and allied health professionals about whether (and how) Seeking Safety supports stabilisation work with people with CPTSD on their caseloads.

6.9.3 Procedures

Flexible interview topic guides will be co-developed with our LEAG. Purposive maximum variation sampling will be used to ensure diverse participant characteristics are included. Sampling will be guided by sufficient 'information power' relevant to the study objectives [28], though we will consult our LEAG about data saturation, or any perspectives on the trial or Seeking Safety we may have missed, before completing data collection. We anticipate up to 20 participant and 4 staff interviews will be required. With informed consent, interviews will be conducted either face to face, by telephone or online via MS Teams, last 30-45 minutes and be audio-recorded, transcribed and anonymised. All CMHT clinicians and allied health professionals in the participating teams will be invited to participate in the brief online survey.

6.9.4 Analysis

Transcripts will be analysed using thematic analysis [29]. Data collection and analysis will proceed concurrently and will be underpinned by the Theoretical Framework of Acceptability [30]. Analysis will be led by the Trial Manager, with a sub-set of the data independently coded by Co-Is to enhance trustworthiness of the analysis process and to contribute to theme development. Any discrepancies will be discussed and incorporated into the final coding framework. Findings will be considered in relation to quantitative results and provide an enhanced understanding of the acceptability and feasibility of the trial processes and identify potential refinements to trial processes and intervention delivery in the main trial.

6.10 Withdrawal criteria

There are a limited set of exceptional circumstances in which participants could be withdrawn from the intervention. This will primarily be if there are severe adverse events for a participant related to the intervention. A clinician responsible for a participant could withdraw them from the intervention if several severe adverse events were to occur.

The Trial Steering Committee (TSC) will review serious adverse events related to the intervention throughout the trial. The TSC can make a decision to either recommend withdrawal of participants from the intervention or request a premature end to the trial if evidence suggests that the intervention is harmful.

Participants who have/have been withdrawn from the intervention will continue to be followed up by researchers unless they also choose to also withdraw from the trial.

6.11 End of trial

The end of the trial is defined as the point at which the last participant has completed the 12-month post-randomisation follow-up or the last participant has been interviewed in the qualitative component, whichever occurs last.

7 TRIAL TREATMENTS

Seeking Safety is a manualized, integrated, present-focused coping skills model to address CPTSD and substance use or other behaviours at the same time [3]. Seeking Safety is delivered in groups of 8-12 people in up to 20 weekly sessions of 90 minutes and covers four domains (cognitive, behavioural, interpersonal and case management) which include topics around developing coping strategies, broadening support networks of individuals by helping them to grow confidence in personal relationships and in supportive settings in the community (table 5).

Table 5 Seeking Safety topics

Domains (cognitive, behavioural, interpersonal, or a combination) are listed in parentheses.

(1) Introduction to treatment / Case management This topic covers: (a) Introduction to the treatment; (b) Getting to know the patient; and (c) Assessment of case management needs.
(2) Safety *(combination)* Safety is described as the first stage of healing from both PTSD and substance abuse, and the key focus of this treatment. A list of over 80 *Safe Coping Skills* is provided, and patients explore what safety means to them.
(3) PTSD: Taking Back Your Power *(cognitive)* Four handouts are offered: (a) "What is PTSD?"; (b) "The Link Between PTSD and Substance Abuse"; (c) "Using Compassion to Take Back Your Power"; and (d) "Long-Term PTSD Problems". The goal is to provide information as well as a compassionate understanding of the disorder.
(4) Detaching from Emotional Pain: Grounding *(behavioural)* A powerful strategy, "grounding", is offered to help patients detach from emotional pain. Three types of grounding are presented (mental, physical, and soothing), with an experiential exercise to demonstrate the techniques. The goal is to shift attention toward the external world, away from negative feelings.
(5) When Substances Control You *(cognitive)* Eight handouts are provided, which can be combined or used separately: (a) "Do You Have a Substance Abuse Problem?" (b) "How Substance Abuse Prevents Healing From PTSD"; (c) "Choose a Way to Give Up Substances"; (d) "Climbing Mount Recovery", an imaginative exercise to prepare for giving up substances; (e) "Mixed Feelings"; (f) "Self-Understanding of Substance Use"; (g) "Self-Help Groups"; and (h) "Substance Abuse And PTSD: Common Questions".
(6) Asking for Help *(interpersonal)* Both PTSD and substance abuse lead to problems in asking for help. This topic encourages patients to become aware of their need for help and provides guidance on how to obtain it.

(7) Taking Good Care of Yourself *(behavioural)* Patients are guided to explore how well they take care of themselves, using a questionnaire listing specific behaviors (e.g., "Do you get regular medical check-ups?"). They are asked to take immediate action to improve at least one self-care problem.
(8) Compassion *(cognitive)* This topic encourages the use of compassion when trying to overcome problems. Compassion is the opposite of "beating oneself up", a common tendency for people with PTSD and substance abuse. Patients are taught that only a loving stance toward the self produces lasting change.
(9) Red and Green Flags *(behavioural)* Patients are guided to explore the up-and-down nature of recovery in both PTSD and substance abuse through discussion of "red and green flags" (signs of danger and safety). A *Safety Plan* is developed to identify what to do in situations of mild, moderate, and severe relapse danger.
(10) Honesty *(interpersonal)* Patients are encouraged to explore the role of honesty in recovery and to role-play specific situations. Related issues include: What is the cost of dishonesty? When is it safe to be honest? What if the other person doesn't accept honesty?
(11) Recovery Thinking *(cognitive)* Thoughts associated with PTSD and substance abuse are contrasted with healthier "recovery thinking". Patients are guided to change their thinking using rethinking tools such as *List Your Options*, *Create a New Story*, *Make a Decision*, and *Imagine.* The power of rethinking is demonstrated through think-aloud and rethinking exercises.
(12) Integrating the Split Self *(cognitive)* Splitting is identified as a major psychic defense in both PTSD and substance abuse. Patients are guided to notice splits (e.g., different sides of the self, ambivalence, denial) and to strive for integration as a means to overcome these.
(13) Commitment *(behavioural)* Making and keeping promises, both to self and others, are explored. Creative strategies for keeping commitments, and feelings that can get in the way, are described.
(14) Creating Meaning *(cognitive)* Meaning systems are discussed with a focus on assumptions specific to PTSD and substance abuse, such as *Deprivation Reasoning, Actions Speak Louder Than Words,* and *Time Warp.* Meanings that are harmful versus healing in recovery are contrasted.

(15) Community Resources *(interpersonal)* A lengthy list of national non-profit resources is offered to aid patients' recovery (including advocacy organizations, self-help, and newsletters). Also, guidelines are offered to help patients take a consumer approach in evaluating treatments.
(16) Setting Boundaries in Relationships *(interpersonal)* Boundary problems are described as either too much closeness (difficulty saying "no" in relationships) or too much distance (difficulty saying "yes" in relationships). Ways to set healthy boundaries are explored, and domestic violence information is provided.
(17) Discovery *(cognitive)* Discovery is offered as a tool to reduce the cognitive rigidity common to PTSD and substance abuse (called "staying stuck"). Discovery is a way to stay open to experiences and new knowledge, using strategies such as *Ask Others, Try It and See, Predict,* and *Act "As If"*. Suggestions for coping with negative feedback are provided.
(18) Getting Others to Support Your Recovery *(interpersonal)* Patients are encouraged to identify which people in their lives are supportive, neutral, or destructive toward their recovery. Suggestions for eliciting support are provided, as well as a letter they can give to others to promote understanding of their PTSD and substance abuse. A safe family member or friend can be invited to attend the session.
(19) Coping with Triggers *(behavioural)* Patients are encouraged to actively fight triggers of PTSD and substance abuse. A simple three-step model is offered: change *who* you are with, *what* you are doing, and *where* you are (similar to "change people, places, and things" in AA).
(20) Respecting Your Time *(behavioural)* Time is explored as a major resource in recovery. Patients may have lost years to their disorders, but they can still make the future better than the past. They are asked to fill in schedule blanks to explore issues such as: Do they use their time well? Is recovery their highest priority? Balancing structure versus spontaneity; work versus play; and time alone versus in relationships are also addressed.
(21) Healthy Relationships *(interpersonal)* Healthy and unhealthy relationship beliefs are contrasted. For example, the unhealthy belief "Bad relationships are all I can get" is contrasted with the healthy belief "Creating good relationships is a skill to learn." Patients are guided to notice how PTSD and substance abuse can lead to unhealthy relationships.

(22) Self-Nurturing *(behavioural)* Safe self-nurturing is distinguished from unsafe self-nurturing (e.g., substances and other "cheap thrills"). Patients are asked to create a gift to the self by increasing safe self-nurturing and decreasing unsafe self-nurturing. Pleasure is explored as a complex issue in PTSD/substance abuse.
(23) Healing from Anger *(interpersonal)* Anger is explored as a valid feeling that is inevitable in recovery from PTSD and substance abuse. Anger can be used constructively (as a source of knowledge and healing) or destructively (a danger when acted out against self or others). Guidelines for working with both types of anger are offered.
(24) The Life Choices Game *(combination)* As part of termination, patients are invited to play a game as a way to review the material covered in the treatment. Patients pull from a box slips of paper that list challenging life events (e.g., "You find out your partner is having an affair"). They respond with how they would cope, using game rules that focus on constructive coping.
(25) Completion Patients express their feelings about the ending of treatment, discuss what they liked and disliked about it, and finalize next steps. An optional Completion Letter can be read aloud to patients as a way to validate the work they have done.

Participants will also have individual sessions with a trained group leader before starting the group and on completion. The initial session helps to prepare the participant for entering the group programme and enables both the group leader and participant to discuss their expectations; the final session provides the opportunity for both to debrief and to discuss how the participant will use the skills and strategies acquired in their life going forward.

Delivery of the intervention will be in mixed sex groups. These groups will be held online in one site and in-person in the other site to evaluate the feasibility of different modes of delivery. In the site with in-person delivery, there will also be an option for a women-only online group. Our pilot work found that mixed sex groups contributed to ongoing trauma for some women through the gendered presentation of symptoms and led to higher drop-out, whereas the discussion of topics and management of group dynamics is optimised in sex-based groups [15]. However, in this feasibility trial, we will test both women-only and mixed sex groups. Staff delivering Seeking Safety will receive two days of intervention training led by the programme developers.

7.1 Fidelity

A random selection of 10% of group sessions will be audiotaped to ensure treatment manual adherence (consent for this will be sought at entry into the trial). Two raters will rate adherence to the treatment manual and give feedback to the healthcare professionals delivering them. The raters will be trained to evaluate adherence to the treatment manual by the programme developer, Dr Lisa Najavits (or a member of her team), who has confirmed her willingness to undertake this.

7.2 Waiting list control group

Participants randomised to the wait-list control group will receive CMHT care as usual or remain on the waiting list for psychological therapy. They will be offered Seeking Safety at the end of the study after all follow-up data has been collected.

Intervention and control group participants will not be prevented from seeking additional treatment for CPTSD or other problems after consenting and providing baseline data (though they will not be eligible to participate in the study if they are already receiving another intervention or therapy for CPTSD). If they are offered psychological therapy, their participation in the trial will not prevent them from starting this. We will collect data on services, treatments and interventions accessed during the trial in both groups and will review how this information could be used in a sensitivity analysis in the full trial.

8 SAFETY REPORTING

8.1 Definitions

Term	Definition
Adverse Event (AE)	Any unfavourable and unintended sign or symptom that develops or worsens during trial participation, whether or not it is considered to be related to the trial intervention. In all instances, it will be up to the site PI (or appropriate delegate, e.g. clinician) to determine whether the person's change in health is related to the trial. AEs are not continuous and persistent disease or symptoms, present before the trial, which fail to progress; signs or symptoms of the condition being studied; or treatment failure.
Adverse Reaction (AR)	An untoward and unintended response in a participant to the intervention. A causal relationship between the trial intervention and an AE is at least a reasonable possibility, i.e. the relationship cannot be ruled out. All cases judged by either the PI or their delegate as having a reasonable suspected causal relationship to the trial intervention qualify as adverse reactions.
Serious Adverse Event (SAE)	A serious adverse event is any untoward occurrence that: • results in death • is life-threatening[1] • requires inpatient hospitalisation or prolongation of existing hospitalisation • results in persistent or significant disability/incapacity • consists of a congenital anomaly or birth defect [1] The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe. [2] The definition of hospitalisation is an unplanned overnight stay. Note, however, that the patient must be formally admitted – waiting in outpatients or an Accident & Emergency Department (A&E) would not count as hospitalisation (even though this can sometimes be overnight). Prolongation of an existing hospitalisation qualifies as a SAE. Planned hospital stays would not be counted as SAEs. Also, if patients had a day-case operation, this would not qualify as hospitalisation. However, if a planned operation was brought forward because of worsening symptoms, this would be considered as an SAE. Hospitalisations for the purpose of the intervention are an exception to SAE reporting unless complications occur.
Serious Adverse Reaction (SAR)	An adverse event that is both serious and, in the opinion of the reporting Investigator, believed with reasonable probability to be due to the trial intervention, based on the information provided.

Suspected Unexpected Serious Adverse Reaction (SUSAR)	A serious adverse reaction, the nature and severity of which is not consistent with the information about the intervention, which is unexpected.
Accidents, Incidents or near Misses	The AIMS system is common in many NHS Trusts and implements an NHS Trust's policy on Incident Reporting – including relevant AEs that occur in relation to research and during normal clinical practice.

Classification of severity

Mild event:	An event that is easily tolerated by the participant, causing minimal discomfort and not interfering with everyday activities.
Moderate event:	An event that is sufficiently discomforting to interfere with normal everyday activities.
Severe event:	An event that prevents normal everyday activities.

Classification of relatedness

Not related	Temporal relationship of the onset of the event, relative to administration of the intervention, is not reasonable or another cause can by itself explain the occurrence of the event.
Unlikely to be related	Temporal relationship of the onset of the event, relative to administration of the intervention, is unlikely and it is likely there is another cause which can by itself explain the occurrence of the event.
Possibly related	Temporal relationship of the onset of the event, relative to administration of the intervention, is reasonable but the event could have been due to another, equally likely cause.
Probably related	Temporal relationship of the onset of the event, relative to administration of the intervention, is reasonable and the event is more likely explained by the intervention than any other cause.
Definitely related	Temporal relationship of the onset of the event, relative to administration of the intervention, is reasonable and there is no other cause to explain the event, or a re-challenge (if feasible) is positive.

8.2 Identification of adverse events

Adverse Events (AEs) are expected to occur throughout the course of the trial. AEs may be volunteered by the participant or detected by a member of the research team or a clinician through questioning or observation, during either the intervention sessions or the follow-up contact. The local PI is responsible for assessing all AEs that they become aware of for their participants during the trial, i.e. those occurring from when a participant signs the written consent form until the final 12-month follow-up time point. Recording and reporting details of AEs are outlined below (section 8.4). The research team will communicate with the local PI if additional information is required, e.g. to ascertain the nature and severity of an AE. If a participant attends a routine (i.e. non-trial related) appointment and an AE is reported, the local research team will assess and log this according to trial recording and reporting procedures; see below.

8.3 Operational definitions for (S)AEs

The PI (or appropriate delegate, e.g., clinician) is responsible for assessing all AEs and categorising whether they are serious, expected, and related. A list of events that can be expected during this trial, or within this patient population can be found below. Other factors such as participant history should not be taken into account.

For the participants in this study, (S)AEs are expected due to the participants' diagnosis.

The following events can be expected during this trial, or within this service user population:

- A significant mental health episode (e.g. suicide, suicide attempts, mental health related hospital admissions i.e. self-harming).
- A sustained and clinically significant deterioration i.e. a worsened mental state, which can include the emergence of new symptoms.
- An event with a significant negative impact for an individual in terms of mental and physical wellbeing, and/or social/everyday function (e.g. safeguarding concerns).
- Substance use, impulsive behaviour or behaviour which may negatively impact on others.

8.4 Recording and reporting non-serious AEs

A non-serious AE is an adverse event which does not satisfy the above definition of an SAE.

Only non-serious AEs that are assessed as being possibly, probably or definitely related to the intervention and/or study procedures, will be recorded in the relevant study documentation (e.g., CRF). They should also be recorded in the participant's clinical notes by a suitable member of the local research team. The participant should be followed up by the local research team until the event subsides. The recording framework for non-serious AEs is shown in Figure 1. A record of all recordable AEs must be kept in the ISF.

If the event is defined as 'serious' (SAE) the local research team should proceed to follow reporting procedures for SAEs, outlined below (see section 8.5).

CRF data capture will include (as a minimum):

- A description of the event
- date (and time where known) that it started and stopped
- severity of the event
- relatedness of the event
- details of any actions taken in response to the event
- outcome of the event (including details about sequelae, where relevant).

Non-serious AEs (with the exception of new mental health diagnoses/symptoms) that are unrelated to the intervention, do not need to be recorded.

The central research team will prepare regular summary reports of all recorded non-serious AEs for discussion at relevant oversight meetings, including with the Sponsor.

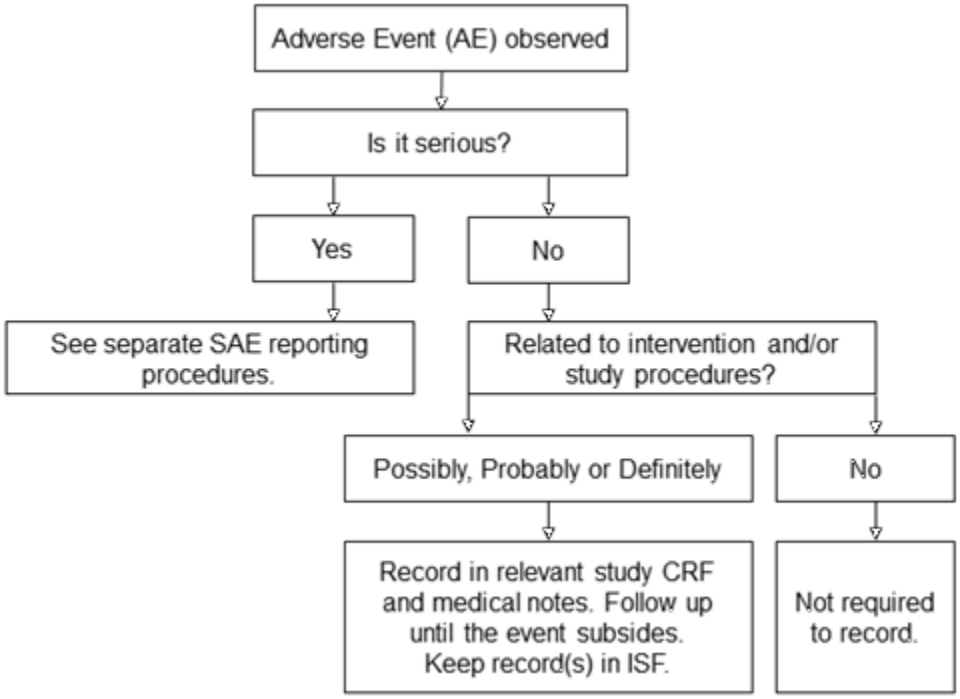


Figure 1 Recording framework for AEs assessed as non-serious

8.5 Recording and reporting Serious AEs (SAEs)

Local research teams will record all SAEs in the SAE Summary Log and will be filed in the ISF. A copy of this will be securely transferred to the central trial team (study office) on a regular basis (e.g. monthly) for monitoring and reporting purposes. The central trial team will prepare regular summary reports of SAEs for discussion at relevant trial oversight meetings, including with the Sponsor.

Furthermore, all SAEs will be recorded on relevant study documentation (e.g. CRF). They should also be recorded in the participants' clinical notes, by the local research team. The participant should be followed up by the local research team until the event subsides. The PI, or delegate, should complete the overall assessment. Information not available at the time (such as test results) must be forwarded once available.

- Expected SAEs will be recorded (as noted above) and reported to the Sponsor routinely by the central trial team, but do not require expedited reporting to the Sponsor *unless* they are fatal.
- Expected SAEs which are fatal will be reported to the Sponsor within 24 hours of staff becoming aware of the event, as detailed below.
- Unexpected SAEs will be reported to the Sponsor within 24 hours of staff becoming aware of the event. Any unexpected SAEs which are causally related to the intervention/ research procedures will also be reported to the REC immediately (must be within 7 days if fatal, or 15 days if non-fatal) by the central trial team.

All SAEs that require expedited reporting to the Sponsor (i.e. expected SAEs which are fatal, and all unexpected SAEs) must be documented on the full SAE/SAR Initial Report Form, which is provided by the central trial team. (An initial report may be provided orally but a written SAE/SAR Initial Report Form must be completed within 24 hours of staff becoming aware of the event). Reporting process:

- Sites should scan and email the form, with high importance, to the (i) Sponsor, (ii) The Trial Manager, and (iii) cc'd Prof Martin Webber, Chief Investigator; see 'Key Trial Contacts' for contact details).

(Please note: typical University staff working hours are Monday to Friday, 09:00-17:00 (subject to variation). In the event of University closure dates or limited availability, an out of office automatic response will notify the site of alternative contact details/arrangements).

- The Sponsor and/or central trial team will confirm receipt and, if required, forward the completed form to REC within the reporting periods (see below).

For each SAE reported to the Sponsor, the following information (as a minimum) will be collected:

- Full details in medical terms and case description
- Event duration (start and end dates, if applicable)
- Action taken
- Outcome
- Seriousness criteria
- Causality (i.e. relatedness to research procedures), in the opinion of the PI
- Whether the event would be considered expected or unexpected.

Each SAE will be reported separately and not combined on one SAE form.

Any change of condition or other follow up information relating to a previously reported SAE should be documented on a separate trial SAE Follow Up Report Form provided by the central trial team.

As above, sites should scan and email the form to the relevant personnel who will confirm receipt, and if required, forward it to the REC within the necessary timeframes.

Events will be followed up until the event has resolved or a final outcome has been reached.

Figure 2 below summarises the SAE safety reporting requirements.

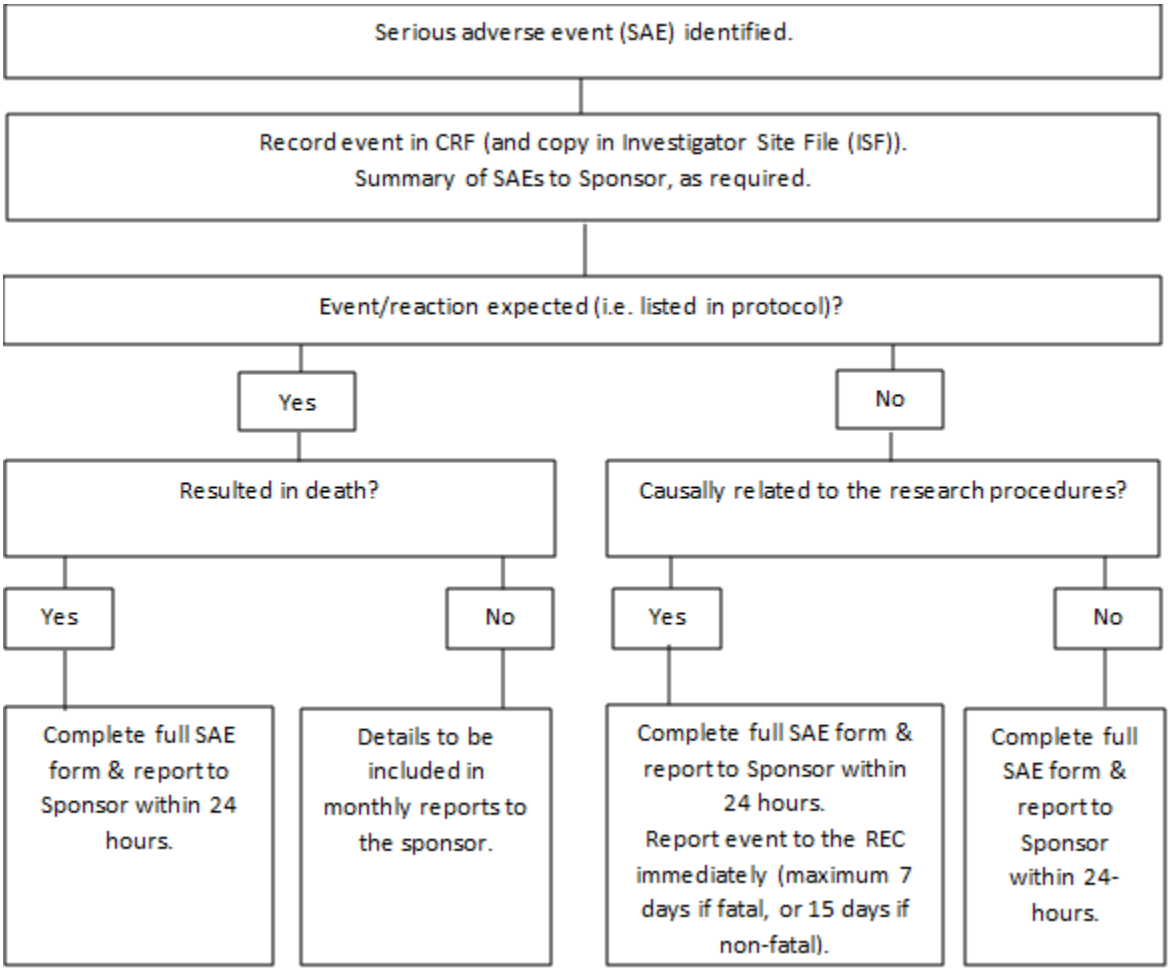


Figure 2 Overview of safety reporting requirements for AEs assessed as being serious (SAEs)

8.6 Responsibilities

All adverse events will be documented and reported in accordance with South West Yorkshire Partnership NHS Foundation Trust Safety Reporting Standard Operating Procedure (SOP) and as above, agreed by the Sponsor.

Principal Investigator (PI)/site research staff. PIs and research staff (or suitably trained delegates) at each site will be checking for AEs when participants attend for intervention/follow-up, and at specified data collection points. The appropriate persons will be responsible for:

- Using medical judgement in assessing and assigning seriousness, causality and expectedness
- Ensuring that all appropriate AEs are documented
- Ensuring that all SAEs are recorded and reported as per the procedures noted above, including the provision of further follow-up information as soon as available
- Ensuring that SAEs are chased with the Sponsor/central trial team if a record of receipt is not received within 2-working days of initial reporting
- Investigators should also comply with any internal SAE reporting requirements within their host institution

Chief Investigator (CI). The CI (or agreed delegate) will be responsible for:

- Clinical oversight of the safety of participants participating in the trial, including an ongoing review of the risk/benefit
- Using professional judgement in assessing and assigning seriousness, causality and expectedness of SAEs where it has not been possible to obtain local medical assessment
- Immediate review of SAEs requiring expedited reporting
- Ensuring safety reports are prepared in collaboration with appropriate members of the TMG group for the relevant oversight committees and regulatory authorities
- Expedited reporting of SAEs to the REC within required timelines
- Notifying PIs of SAEs that occur within the trial (where applicable)
- Central data collection of SAEs

Trial Manager. The Trial Manager will provide a summary of S/AEs to the TSC and Sponsor as required.

9 STATISTICS AND DATA ANALYSIS

9.1 Sample size

As this is a feasibility trial a formal sample size calculation based on statistical power to detect a specified treatment effect size is not appropriate.

Feasibility outcomes such as the consent rate and retention rate will be calculated with 95% confidence intervals. A minimum of 56 participants recruited from a potential population of 256 participants would have a 95% confidence interval of 15% to 25%. If the retention rate for the 56 recruited participants is 80% the confidence interval will be from 30 to 50. Across the two sites, we estimate that about 100 people with CPTSD could be eligible. Our recruitment target of 56 participants is achievable as there has been strong interest in the Seeking Safety groups as limited other treatment options are available. This assumes a participation rate of one-third, which appears achievable in this population [31].

9.2 Statistical analysis plan

Data will be analysed and reported following the CONSORT guidance extension to feasibility studies [25, 26], including a CONSORT flow diagram and focussing principally on descriptive statistics on key feasibility parameters. We will assess the feasibility and acceptability of the trial design by calculating proportion (and 95% CIs) of participants:

- consenting
- completing baseline measures and randomised
- receiving a dose of the intervention - i.e. attending at least six out of 20 sessions
- completing follow-up assessments

For each outcome, the proportion with complete data will be reported in addition to descriptive statistics (means, medians, or proportions), together with precision estimates (SD, IQR or 95% CIs). The effect of treatment on outcomes will be estimated on an intention-to-treat basis using estimates and CIs only, since the study has not been powered for formal statistical testing. A full statistical analysis plan will be written before the analysis takes place.

9.3 Progression to full trial

Progression to a full scale RCT will be based on traffic light criteria around a) recruitment, b) adherence (attending at least 6 sessions) and c) completion of follow-up data (see Table 6 below). Assuming we meet our progression criteria, we aim to submit a grant application to the NIHR Health Technology Assessment (HTA) programme, for a definitive trial. If there is a mix of red/amber and green criteria the progression decision will be discussed with the TMG and TSC.

Table 6 Progress to full trial criteria

	Participants	Anticipated action
Go (Green)	• **Recruitment:** ≥45% (n=≥25) of expected recruitment over 6 month period. • **Adherence:** ≥75% adherence to the intervention.	Continue to main trial.

	• **Follow Up:** ≥80% of data for suggested primary outcome at follow-up	
Amend (Amber)	• **Recruitment:** 30-45% (n=17-25) of expected recruitment target. • **Adherence:** 25-74% adherence to the intervention. • **Follow Up:** 60-80% of data for suggested primary outcome at follow-up	Identify remediable factors, discuss with TMG and TSC.
Stop (Red)	• **Recruitment:** <30% (n=<17) of expected recruitment target. • **Adherence:** <25% adherence to the intervention. • **Follow Up:** <60% of data for suggested primary outcome at follow-up	Do not progress to main trial, unless there is a strong case that unanticipated remediable factors have been identified and can be addressed after further discussion with the funder.

10 ECONOMIC EVALUATION

We will assess the feasibility of estimating the cost-effectiveness of the intervention as part of a subsequent full trial. This feasibility study will be used to test the methods for a subsequent, policy-relevant, cost-effectiveness analysis (CEA) of Seeking Safety, compared to usual care. It will produce preliminary results to explore the resource use and costs involved in supplying the intervention, resources used and associated costs, and quality-adjusted life-years (QALYs). The perspective of the cost-effectiveness analysis will be of the UK NHS and personal social services [32] and therefore data on resource use and outcomes relevant to this perspective will be collected to explore the feasibility of collecting these data.

We will explore the contribution of other sectors to the care and wellbeing of these participants. To gain understanding about broader resource use and cost, we will test the feasibility of collecting other relevant resource use comprising service use from other statutory sectors, including criminal justice services, as well as the third sector service use and private out-of-pocket payments made to access the intervention. Findings from the health economics feasibility study will be presented in disaggregated form so that cost and outcome data will not be synthesised. The reporting of the economic data will be informed by the CHEERS 2022 Checklist [33].

The objectives in this study are to identify and establish feasibility in terms of the health economics components of the data collection to:

- identify, measure and value NHS and personal social services resource use for participants (based on adapted CSRI [22]). Also, to consider use of criminal justice services, third sector services use and out of pocket costs incurred by them
- identify sources of national-level unit costs of health and social care services [34]
- refine the methods for collecting data on health, social care and broader participant and societal resource use
- assess the feasibility of collecting participant-level quality of life measure (EQ-5D-5L) to inform a future full economic evaluation

10.1 Costing the intervention

We will investigate the types of resources used to deliver the intervention for costing in the full trial. This will involve engaging with intervention developers and providers, as well as team managers at the two sites, to complete a short questionnaire to collect this information. This will include, for example, the use of staff time, travel, materials, documentation and consumables. We will document the staff time, in terms of per-participant contact, non-contact time, and any additional time in relation to the delivery of the intervention. Training and supervision resources will also be documented. To aid transferability, nationally recognised UK unit costs for health and social care services [34] will be applied to this resource use data. Where national costs are not available, costs will be identified in consultation with the intervention developers and providers. The mean cost per participant of the intervention will be estimated.

10.2 Health, social care and wider societal resource use

A modified version of the CSRI [22] will be used to measure resource use. Relevant items will be identified from the Database of Instruments for Resource Use Measurement (DIRUM, [35]) and relevant literature. Participants will be asked to complete the self-report questionnaire at baseline, end of treatment, and at 6 months post treatment. Unit costs will be applied to the resource use data using the approach outlined for the intervention costing, as above.

10.3 Health outcomes and quality-adjusted life-years

Participants will complete the EQ-5D-5L [20] at baseline, the end of treatment and at 6 months post randomisation. Participant-level QALY weights will be estimated in accordance with current NICE guidance: responses to the EQ-5D-5L will be mapped to the UK tariff of health state values for the EQ-5D-3L using an 'approved' cross-walk algorithm [36].

11 DATA MANAGEMENT

11.1 Data collection tools and source document identification

11.1.1 Source Data

Source data is the first place the data is recorded. Source data for this trial will by default consist of electronic versions of preliminary screening and consent to contact forms, consent form(s), completed questionnaires (paper and/or electronic) and other CRFs designed specifically for the study, and audio-recordings of interviews. However, where electronic data collection is not possible, equivalent paper documents will become the source data. Data obtained by paper will be entered onto the database as soon as practical by the Trial Manager. Any paper documents containing identifiable information will be stored in a locked filing cabinet at the site, which only members of the local research team have access to.

Each participant will be allocated a unique study I.D number at the point of providing informed consent. Participants will be identified in all study-related documentation by (at least) their study I.D number. A record of trial participants' names and contact details, NHS numbers and assigned trial numbers will be retained by the research staff at the site and stored securely for administrative purposes (in the ISF, for example). Personal data entered directly into the password protected database and maintained by the UoY will only be accessible to relevant members of the research team. Any data stored on laptops will be encrypted. Any information that is analysed or transferred outside the European Economic Area (EEA) will be anonymised.

Participants will be informed via the information documents and consent form that personal information such as their name, email address and phone number will be stored on the secure database within the site. Furthermore, for the purpose of conducting the trial randomisation only, participant information (including personal details, such as unique study I.D. number, study site, sex, and date of birth) will be entered into the secure online randomisation system provided by Sealed Envelope™. All data that are entered on to the Sealed Envelope™ system is done so via secure sockets layer (SSL) connections and stored on secure servers located in the UK and Ireland that comply with both UK and EU regulations on data privacy. User-access to the system will be managed by the central trial team (study office).

Information capable of identifying individuals and the nature of treatment received will be held in the database with passwords restricted to trial staff. Information capable of identifying participants will not be removed from clinical sites apart from when securely transferring data to the central trial team at the UoY. This data will not be made available in any form to those outside the trial, with the exception of inspection purposes by the Sponsor and/or other regulatory authorities. Consent forms and clinical letters (and any other documentation) with personal identifiable data will be stored in a locked filing cabinet (or locked equivalent). Participant details will be anonymised in any publications that result from the trial.

Local site teams must keep a paper record of their participants PIL and consent form(s) in their ISF for monitoring purposes, regardless of the method of data collection. Paper-completed CRFs should also be retained in their ISF. To enable remote-working, electronic records will suffice until a time when they can be printed and suitably filed.

11.1.2 Qualitative interview data

Interview data captured on an encrypted audio digital recorder will be uploaded to the UoY secure server as soon as possible after each interview. Audio-recordings will be transcribed by UoY employees or University-approved transcription services. Audio-recordings and transcripts will be

labelled with a unique study I.D number, edited to ensure anonymity of respondents, and stored securely adhering to the University's data storage policies.

Anonymised quotations and parts of voice-modified recordings may be used for training, teaching, research and publication purposes for this and future studies. Anonymised transcripts may be made available to other researchers who demonstrate compliance with legal, data protection and ethical guidelines for purposes not related to this study, subject to individual informed consent from participants (this includes trial participants). At the end of the study, anonymised data (including transcripts of audio-recordings) will be stored in a secure research data storage facility, alongside the other study data.

11.2 Data collection

Data collection is detailed in section 6, above (and throughout).

Data will be recorded directly into the Qualtrics Survey Management system where possible by participants or the Trial Manager. Otherwise, paper CRFs will be used and the data will be entered into Qualtrics as soon as possible following an interview. Any electronic data to be transferred from the site to the central study team at the UoY will be sent by secure email.

11.3 Database platforms

11.3.1 Administrative data

Administrative data relating to trial participants, particularly identifiable data, will be stored in a SQL Server system at SWYT. This information will only be accessible by members of the trial research team. All users will require (at least honorary) contracts with SWYT to access it.

11.3.2 Clinical data

Clinical studies data will be gathered by Qualtrics and exported to Excel for data cleansing. The UoY has set up its own infrastructure so that all systems are hosted at and supported by UoY. The clinical data will be stored in a separate database to the administrative data. Anonymised clinical data is linked by a study participant I.D. If an email address is collected, the 'Email Address' field is flagged as an identifier and not included in the export for the statistician, so the data set can be considered pseudonymised at export and does not need further processing.

11.4 Data storage

University of York is the data controller for this trial. Data will be held at the University of York and will conform to the University of York Data Security Policy and in Compliance with the General Data Protection Regulation (GDPR) as it applies in the UK, tailored by the Data Protection Act 2018.

11.5 Access to data

For monitoring purposes, the CI will allow monitors from the Sponsor (or delegate), persons responsible for the audit and other Regulatory Authorities to have direct access to source data/documents.

The Trial, and Data, Manager (in collaboration with the CI) will manage access rights to the data set. Prospective new users must demonstrate compliance with legal, data protection and ethical guidelines before any data are released.

11.6 Archiving and destruction of trial materials

An archiving plan will be developed for all trial materials. Data will be held in compliance with the Sponsor's SOPs. All research data will be retained in a secure location during the conduct of the trial and for at least 10 years after the end of the trial. Medical case notes containing source data or other trial-related information should be identified by a label (or equivalent for electronic notes, where feasible) "Keep until at least dd/mm/yyyy" where the date given is at least 10 years (or applicable period) after the end of the trial. Data will be kept at the UoY (and/or Sites) for this time and, at the end of the archiving period, will be destroyed by confidential means with the exception of a final trial dataset which will be made available for data-sharing purposes (see section 11.7 below). Where electronic records are in use, UoY's policy will be followed. The approval of UoY as owner of data and SWYT as Sponsor, as well as the CI, will be sought prior to destruction of the data.

Participating sites will be responsible for ensuring that all study records held at site are archived appropriately when notified by the Sponsor / central trial team.

11.7 Access to the final trial dataset

Anonymous research data, which may include qualitative audio-recordings and/or associated data such as anonymised transcripts, will be stored securely and kept for future analysis with participant consent. We anticipate that anonymised trial data will be shared with other researchers to enable international prospective meta-analyses. Members of the TMG will develop a data sharing policy consistent with UoY policy. Data will be kept anonymous on research data storage facility (RDSF). Requests for access to data must be via a written confidentiality and data sharing agreement (DSA) available from the RDSF website which will be confirmed by the CI (or appointed nominee).

The DSA should cover limitations of use, transfer to third parties, data storage and acknowledgements. The person applying for use of the data will be scrutinised for appropriate eligibility by members of the research team.

12 MONITORING, AUDIT & INSPECTION

The trial will be monitored in accordance with the Sponsor's policy, which is consistent with the UK Policy Framework for Health and Social Care Research. All trial related documents will be made available on request for monitoring and audit by the Sponsor, the relevant Research Ethics Committee (REC) and available for inspection by other licensed bodies.

A Trial Monitoring Plan will be developed by the Sponsor and agreed by the TMG and CI based on the trial risk assessment which may include on-site monitoring.

The Sponsor usually delegates some of the monitoring to the central research team. The following checks would be typical:

- That consent is taken by an appropriately authorised person
- That informed consent has been properly documented
- That data collected are consistent with adherence to the trial protocol
- That CRFs are only being completed by authorised persons
- That SAE recording, recording of protocol deviations and reporting procedures are being followed correctly
- That no key data are missing
- That data is valid
- Review of recruitment rates, withdrawals, and losses to follow-up

12.1 Protocol compliance

There will be no prospective, planned deviations or waivers to the protocol. Accidental protocol deviations can happen at any time, but they must be adequately documented on the relevant forms and reported to the CI and Sponsor. In the event of systematic protocol deviations, investigation and remedial action will be taken in liaison with the CI, TMG and the TSC.

A serious protocol breach will be reported to the Sponsor as soon as possible. The Sponsor will determine the seriousness of the breach and whether onward reporting to the REC is necessary.

12.2 Notification of Serious Breaches to GCP and/or the protocol and poor-quality data

A "serious breach" is a breach which is likely to effect to a significant degree:

- the safety or physical or mental integrity of the subjects of the trial; or
- the scientific value of the trial

The Sponsor must be notified immediately of any case where the above definition applies during the trial conduct phase. They will assess the seriousness of any breach as per appropriate Sponsor SOP. Repeated major breaches may be considered serious breaches and notified to the REC and Health Research Authority (HRA).

13 ETHICAL AND REGULATORY CONSIDERATIONS

13.1 Research Governance

The study will be undertaken at two sites within SWYT, subject to appropriate REC approval and HRA approval. The trial will be conducted in accordance with the protocol, the conditions and principles of the Declaration of Helsinki and GCP. Any amendments of the protocol will be submitted to the REC for approval. On request, the study investigators and their institutions will permit trial-related monitoring and audits by the Sponsor and relevant REC by providing direct access to source data and other documents (i.e. patients' hospital notes, where relevant).

13.2 Governance and legislation

This trial will be conducted in accordance with:

- Conditions and principles of Good Clinical Practice (GCP)
- UK Policy Framework for Health and Social Care Research
- Data Protection Act (DPA) 2018
- Mental Capacity Act 2005
- General Data Protection Regulation (GDPR)

Any amendments to the trial must be assessed and approved by the Sponsor prior to submission to the REC and HRA.

Before any site can enrol participants into the trial, the CI or designee will obtain confirmation of capacity and capability (C&C) (or equivalent organisation approval) in line with HRA processes along with other documentation required for the Sponsor to grant sites a green light letter.

For all amendments the CI or designee will confirm with the Sponsor, the HRA (+/- REC) and sites' R&D departments that permissions are ongoing.

This research trial will be conducted in accordance with conditions and principles of GCP. GCP is the international ethical, scientific, and practical standard to which all clinical research is conducted. Compliance with GCP provides public assurance that the rights, safety, and well-being of people taking part (trial participants) are protected and that research data are reliable.

13.3 Research Ethics Committee (REC) review & reports

Ethics review of the protocol for the trial and other trial related participant facing documents (e.g., PIL and consent forms) will be carried out by a UK REC. HRA approval will be sought alongside REC. Any amendments to these documents, after a favourable opinion from the REC/HRA has been given, will be submitted to the REC/HRA for approval prior to implementation.

All correspondence with the REC will be retained in the Trial Master File (TMF)/ISF.

An annual progress report will be submitted to the REC within 30-days of the anniversary date on which the favourable opinion was given, and annually until the trial is declared ended. The CI (or designee) will notify the REC of the end of the trial and if the trial is ended prematurely (including the reasons for the premature termination). Within one year after the end of the trial, the CI will submit a final report with the results, including any publications/abstracts, to the REC.

GCP training will be carried out by certain staff members depending on their delegated responsibilities within the trial, the level of training required will be determined according to the NIHR Delegation and Training Decision Aid. Informed consent to participate in the trial will be sought and obtained according to GCP guidelines.

13.4 Peer review

The proposal for this trial has been peer-reviewed through the NIHR RfPB (UK) peer-review process, which includes independent expert and lay reviewers.

13.5 Public and Patient Involvement

A Lived Experience Advisory Group (LEAG) will be appointed. This will comprise up to eight people with lived experience of CPTSD, including those who have participated in Seeking Safety groups, or their family members / carers. Recruitment of LEAG members will be undertaken by the Research and Development Department in SWYT, who will apply equality and diversity principles in the selection of members to help ensure that the LEAG will be as inclusive and diverse as possible. LEAG members' time will be reimbursed at standard NIHR rates for public contributors. The PPI leads for the trial will bring issues, concerns and feedback from the LEAG to monthly TMG meetings to ensure that the group's discussions are heard in full and acted upon. The impact of the LEAG input into the TMG will be recorded in the meeting minutes.

The LEAG will meet five times during the study, including during study set up, during the recruitment period, during the intervention and before the end of the study. It will advise on interview schedules and topic guides; review recruitment and data collection processes; discuss the progress of the intervention; support the interpretation of the findings; and coproduce outputs including an accessible report.

13.6 Poor quality data

The quality of the trial data will be monitored throughout the trial and data completeness will be reported to the TSC, and any cause for concern over data quality will be highlighted and an action plan put in place.

13.7 Financial and other competing interests

This applies to the chief investigator, site PI, research team members and committee members for the overall trial management. The research team, trial committee members and site PI must disclose any ownership interests that may be related to products, services, or interventions considered for use in the trial or that may be significantly affected by the trial. Competing interests will be reported in all publications and in the final report.

13.8 Risks and benefits

We believe this study does not pose any specific risks to individual participants, nor does it raise any serious ethical issues.

As with all trials the main benefit of participating is an altruistic one to improve care for people with CPTSD.

The PIS will provide clear details of the anticipated risks and benefits of taking part in the study. The risks and benefits of the study will be discussed with potential participants as part of the process of inviting people to take part and providing written informed consent.

13.9 Indemnity

The necessary trial insurance is provided by the Sponsors. The PIS provides a statement regarding indemnity for negligent and non-negligent harm.

13.10 Amendments

Protocol amendments will only be made after discussion within the TMG. They will be drafted by the CI and/or Trial Manager for consideration by the Sponsor. The Sponsor will make the decision about whether an amendment is substantial or non-substantial, in consultation with the CI or TMG if required. If the Sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the Sponsor must submit a valid notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice.

Amendments will be notified to the HRA and communicated to the R&D office and local research team within SWYT to assess whether the amendment affects the NHS permission for that site.

13.11 Post trial care

Participants in the intervention arm will continue to receive care as usual (CMHT care or a waiting list for psychological therapy) after the trial. Participants in the control arm will receive the Seeking Safety group intervention on completion of the trial, in addition to care as usual.

14 DISSEMINATION POLICY

14.1 Dissemination policy

Throughout the study we will seek to develop collaborative relationships with policymakers and people with CPTSD, including members of the LEAG, to shape the direction, delivery and dissemination of our research. We will use our experience, expertise and collaborative networks to disseminate to the following key stakeholders:

Members of the public – we will use our existing social media channels in SWYT and University of York (UoY) to inform people about the study and respond to their questions about it. We will use 'talking head' videos recorded by members of the research team to provide succinct information about the study. These will discuss topics such as CPTSD and how Seeking Safety can help people; what a feasibility trial is and the type of questions it answers; how the research is progressing; and what the findings are, including next steps in the research and dissemination processes. These will be self-produced using equipment available to the research team and will include different formats such as interviews, conversations or straight-to-camera shots. The LEAG will advise on the content of these short videos and will be invited to participate in them if they wish. These short videos will help to build a community of interest throughout the project who we will discuss the findings with at the end, including signposting to written reports and papers.

Users of mental health services – the short videos will also provide relevant information about the study for users of mental health services, including how potential participants in SWYT can get involved. In addition, we will coproduce an accessible report with the LEAG which summarises the main findings of the research for distribution to SWYT patients and for publication on the project webpages. This will be in the form of a downloadable PDF published on the SWYT and UoY websites, though printed copies will be sent to people on request. We will also disseminate the main findings from the study by organising an online meeting for service users, practitioners and members of the public where we will distribute the summary of the findings.

Practitioners and service managers – we will distribute the summary of findings to practitioners and service managers within SWYT and invite them to attend the online meeting.

Policy makers and commissioners – as this is a feasibility study, it will not have immediate impacts on policy, though we will engage with the Department of Health and Social Care to inform them of the findings of the study.

Mental health researchers – we will disseminate our findings through peer-reviewed papers and conference presentations. We have established contact with the developer of Seeking Safety, through whom we will engage with international partners to discuss and share our research findings in an online seminar.

14.2 Outputs

We anticipate the following outputs: short videos throughout the project providing information about the study, reporting progress and sharing findings; a report summarising the findings for patients and practitioners; an online seminar to report the findings; peer-reviewed papers; conference presentations; and a protocol for a full trial for submission to NIHR HTA.

14.3 Authorship eligibility guidelines

The authorship criteria set out by The International Committee of Medical Journal Editors will be followed for publications arising from the study and the final trial report.

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16. APPENDICIES

16.1 Appendix 1 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made

Seeking Safety Feasibility Trial

Project Period: 26 months

Year	Pre-grant phase			2026									2027												2028				
Calendar month	Jan-26	Feb-26	Mar-26	Apr-26	May-26	Jun-26	Jul-26	Aug-26	Sep-26	Oct-26	Nov-26	Dec-26	Jan-27	Feb-27	Mar-27	Apr-27	May-27	Jun-27	Jul-27	Aug-27	Sep-27	Oct-27	Nov-27	Dec-27	Jan-28	Feb-28	Mar-28	Apr-28	May-28
Project month				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
Project Start Date (01/04/2026)				◆																									
PHASE 1 - PREPARATORY PHASE																													
Write detailed protocol																													
Write PIS, consent forms																													
Complete IRAS form																													
Ethics and HRA approval, site approvals																													
Write SOPS - Safety, Adverse Events, Recruitment																													
Database set-up, storage solutions, test randomisation																													
Ensure contracts are in place																													
Recruit and train research staff																													
PHASE 2 - FEASIBILITY TRIAL																													
Recruit 56 participants from two sites												◆																	
Collect quant data (baseline) from 56 participants												◆																	
Randomisation												◆																	
Seeking Safety intervention delivery																													
Collect quant data (end of treatment) from 56 participants																		◆											
Collect quant data (6 mth post-treatment) from 56 participants																								◆					
Qualitative study with up to 20 service users and 4 clinicians																													
Compile findings - analysis and prep for HTA application																													
Submit final report																													
Project End Date (31/05/2028)																													◆
PPI & STEERING MEETINGS																													
Trial Management Group meetings				•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Lived Experience Advisory Group meetings						•						•						•						•					•
Trial steering committee meetings						•						•						•						•					•