

Participant Information Sheet

Project Title (Full) Seeking Safety group intervention for complex post-traumatic stress disorder: a feasibility randomised controlled trial.

Ethics Approval

This study has been approved by the South Central Oxford C Research Ethics Committee.

Invitation to participate

We would like to invite you to take part in this study. You have been asked to take part in this study as you have symptoms of complex trauma. Please take the time to read this information carefully and discuss it with others if you wish.

Do I have to take part in this project?

No. You do not have to agree to participate in this study and this will not affect any care, support or treatment you are receiving or your position on any waiting list. The decision to take part is entirely yours. If you do decide you would like to be involved, you will be required to sign a consent form. However, you are still free to withdraw your consent at any time from the study without giving a reason, which will not affect your ongoing or future treatment or support. If you choose to withdraw from the study, your data will be retained.

To withdraw from the study, please contact the Trial Manager. Contact details can be found at the bottom of this information sheet.

Background to the research

People who have been through a number of traumatic experiences may suffer from long-lasting severe distress and difficulties. Sometimes they try to cope with these by using behaviours that can get in the way of them making progress towards recovery. For example, they may use drugs or alcohol, or show other risky behaviours. Whilst these behaviours may help the person feel better for a short period, they tend to worsen the person's overall mental health in the long term.

There is a lack of effective treatments for people with complex post-traumatic stress disorder. However, a group programme - 'Seeking Safety' - has been developed in the United States, where it has been effective in addressing both trauma and substance use. In the UK it has been piloted in the NHS with some promising outcomes, though has not yet been tested rigorously.

This is a small study in one Mental Health NHS Trust to test the feasibility of a larger trial across many locations. It will involve people with complex trauma and substance use, or other coping behaviours, from community mental health teams or psychology waiting lists. Participants will be allocated at random to receive Seeking Safety sessions either during the study or at the end of it. Participants in both groups will complete questionnaires when they are allocated to a group; at the end of the Seeking Safety groups (six months later); and six months following this. These will ask about their mental health; substance use and

use of health and social care services. The responses from both groups will be compared. Participants will receive a £30 shopping voucher for each questionnaire they complete.

We will also interview staff and some participants about their experiences of participating in the trial to see if anything needs to change for a larger study.

What have service users said about why this study is important?

Seeking Safety provides support for people who are otherwise unable to access mental health care and treatment. It is not widely used in the NHS, but those who have experienced it have reported its benefits. For example, one person has said:

“Before I received treatment through the Seeking Safety group I was constantly engaging in maladaptive behaviours without understanding why this was the case. Participating in the treatment helped me to understand that I was experiencing trauma and the casual link between trauma and substance abuse. Moreover, the treatment taught me practical techniques to break the cycle of unsafe behaviours and replace them with safe practices.”

Both service users and healthcare professionals have helped to design this study.

Who is leading this study?

University of York in collaboration with South West Yorkshire Partnership Teaching NHS Foundation Trust (SWYT), Psychology and Research and Development team, are leading this study.

What are we aiming to find out from this study?

The aim of this study is to understand whether it is feasible for individuals and healthcare professionals to use Seeking Safety as a treatment to improve mental health outcomes for individuals with complex trauma. It also aims to understand if it is feasible to evaluate outcomes of this when compared to treatment as usual.

What would taking part involve?

You will be randomly allocated to one of two groups. The first group will complete the Seeking Safety sessions during the study (intervention group). The other group will continue to receive their usual care throughout the study (wait list control group). The control group will then be offered the Seeking Safety Sessions at the end of the study.

The intervention group will start the Seeking Safety sessions within approximately 6 months.

The waiting list control group will start the Seeking Safety sessions within approximately 20 months.

You will be randomly allocated to a group. This means that you have a 50/50 chance of being in either group. The decision will be made by a computer. Randomisation will take place once we have enough participants to form a group so there may be a short delay at this stage. We will contact you to let you know what group you have been allocated to. You can also contact the Trial Manager for an update or if you have any questions.

Both of the study groups are equally important and necessary for us to run the study. At the end of the study, we will compare the two groups to see if there are any differences between those participants who completed the Seeking Safety sessions and those who are yet to start Seeking Safety.

Participants in both groups will continue to receive the care and support they are currently receiving (e.g. from your GP, mental health team or any other health care professionals).

The Seeking Safety sessions will take place weekly for 60-90 minutes for up to 20 sessions. The group will meet online [site 1] / face to face, with a women-only online option [site 2] [delete as applicable].

Sessions will cover a range of topics, with chance for discussion and reflection from the group. The topics will include:

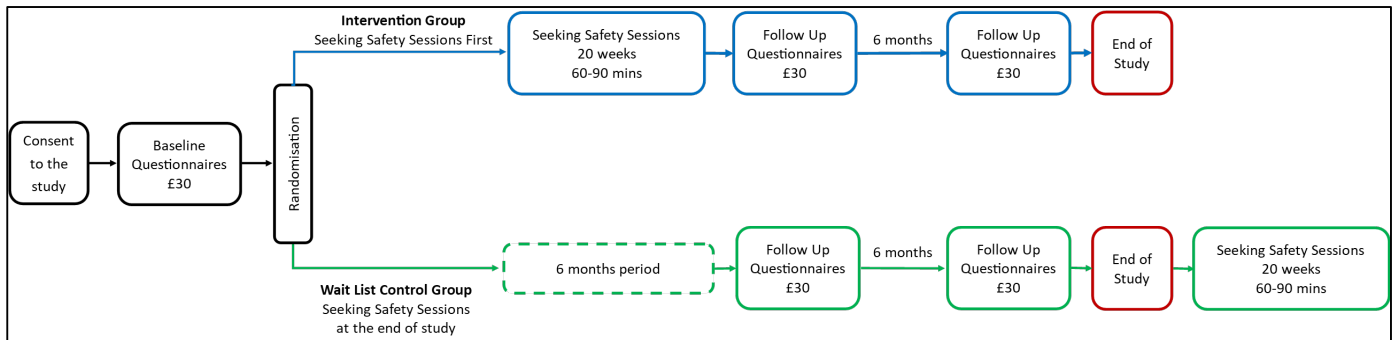
- Introduction to Seeking Safety treatment
- Safety – what it means to you
- PTSD: Taking Back Your Power
- Detaching from Emotional Pain: Grounding
- When Substances Control You
- Asking for Help
- Taking Good Care of Yourself
- Compassion for yourself
- Red and Green Flags
- Honesty
- Recovery Thinking
- Integrating the Split Self
- Commitment
- Creating Meaning
- Community Resources
- Setting Boundaries in Relationships
- Discovery
- Getting Others to Support Your Recovery
- Coping with Triggers
- Respecting Your Time
- Healthy Relationships
- Self-Nurturing
- Healing from Anger
- The Life Choices Game
- Moving on

A small number of Seeking Safety sessions will be audio recorded. This is to make sure the facilitators are delivering the sessions as intended. We will tell you when a session is being recorded. The recordings will not contain any identifiable information and will not be transcribed. The recordings will be reviewed by a suitably trained member of our study team. Once reviewed, the recordings will be deleted.

As well as the feasibility outcomes, we will collect data on the clinical outcomes of participants in the study at baseline, end of treatment (after six months) and at the end of a six-month follow-up period. You will be

asked to complete some questionnaires measuring: PTSD symptoms; substance use; mental wellbeing; social functioning; health-related quality of life; capability wellbeing; and service use. You will receive a £30 shopping voucher for each interview or questionnaire you complete.

Study flow diagram



Who can attend the Seeking Safety groups?

You, as the person with complex trauma.

Can I stop attending the Seeking Safety groups?

Yes, we understand that the ability to commit to attending Seeking Safety group sessions can change for various reasons. If you miss some sessions, you will not be excluded and can re-join the group at any point during the six month intervention period. Please contact us if you are not able to attend or would like to stop attending the group. It will not affect your ability to participate in the study.

How and what information will we use?

You will provide data in questionnaires as part of the study. Also, some information from your medical record will be used, such as medication and treatments you have received. However, any information collected will be anonymised so you cannot be identified and will not be shared with anyone outside of the research team.

If during the study, you lose the capacity to consent, you will be withdrawn from the study. The data already collected as part of the study will be retained and used. No further data will be collected.

How will we use information about you?

We will need to use information from you and from your medical records for this research project.

This information will include your initials, NHS number, name, and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

South West Yorkshire Partnership Teaching NHS Foundation Trust is the sponsor of this research.

South West Yorkshire Partnership Teaching NHS Foundation Trust is responsible for looking after your information. We will not share your information related to this research project with any other organisations.

We will keep all information about you safe and secure by:

- Using secure online platforms for data collection
- Using encrypted audio recorders
- Storing data on secure password-protected servers
- Any hard copies of documents will be stored in locked filing cabinets and only accessible to trial researchers
- Keeping personal data separate from participant's responses

Your data will not be shared outside the UK.

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 10 years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

- you can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have
- you have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- our leaflet www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to research@swyt.nhs.uk , or
- by ringing us on 01924 316 289
- by contacting our Data Protection Officer & Information Governance lead on Rachael.Smith@swyt.nhs.uk / information.Governance@swyt.nhs.uk

What are the possible benefits for me if I take part in this study?

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

What are the possible disadvantages?

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

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

Confidentiality arrangements

In this research study we will use information from your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. All information which is collected as part of this study will be kept strictly confidential. Your name will be removed so that you cannot be recognised. Once all the information has been analysed any remaining information, including any audiotape recordings, from the study will be destroyed. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. We will make sure no-one can work out who you are from the reports we write.

Where can I find out more about research in general?

There is currently no single organisation in the UK, however you may contact the Research & Development (R&D) Department of your local hospital or University which may be able to guide you further.

What will happen to the results of the study?

The results of the study will be written up and presented in research reports, journal articles and conferences.

Participants will have the option to hear about the results of the research. Final study findings will be sent to participants via post or email using contact details collected as part of the study. You can also contact the Trial Manager for more information regarding the results.

What if something goes wrong?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be fully addressed. In the unlikely event of a problem, please raise your concerns in the first instance with the Principal Investigator (that is the lead researcher), Professor Martin Webber or the Trial Manager. Contact details are below. If you wish to make a more **formal complaint**, please contact the hospital's Patient Advice and Liaison Service (available 9 am to 4 pm Monday to Friday, closed on bank holidays).

PALS,
Customer services,
South West Yorkshire Partnership
Teaching NHS Foundation Trust,
Block 10, Fieldhead Hospital,
Ouchthorpe Lane,
Wakefield, WF1 3SP

Email: customerservices@swyt.nhs.uk

Tel: 0800 587 2108 or 01924 316060

Which insurance provisions are in place?

If something does go wrong, and you are harmed during the research, and this is due to someone's negligence, you may have grounds for legal action and compensation against the Sponsor, South West Yorkshire Partnership Teaching NHS Foundation Trust. The normal National Health Service complaints mechanism will still be available to you.

Contact details

Trial Manager

Research & Development
South West Yorkshire Partnership
Teaching NHS Foundation Trust,
Block 9, Fieldhead Hospital,
Ouchthorpe Lane,
Wakefield, WF1 3SP
Email: research@swyt.nhs.uk

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Thank you for reading this.

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