UNIVERSITY OF LINCOLN

PROTOCOL

Using Narrative Exposure Therapy to treat Violent Offenders with Post Traumatic Stress and Emotion Dysregulation: A single case study series.

Protocol Version ***draft*** 4

Date 08.03.26

IRAS Project ID	366069
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Funder	University of Lincoln

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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the Study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement(s).

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 investigation without the prior written consent of the Sponsor

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

Chief Investigator:

Signature: .R.Watson..... Date: 15/09/25..

Name: Rebecca Watson

Supervisor:

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

Name: Professor Thomas Schroder

Second Supervisor:

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

Name: Dr Stephanie Lane

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STUDY/TRIAL CONTACTS

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Student	Trent Doctorate in Clinical Psychology

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FUNDER DETAILS

FUNDER(S)	FINANCIAL AND NON FINANCIALSUPPORT GIVEN
N/A	**NHS England via the Trent DClinPsy Programme**

SUPPLY DETAILS

SUPPLIES
Heart Rate Variability Monitor – Polar H10 Heart rate monitor NET Materials inc. flowers and stones and string for the timeline NET Manual

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STUDY/TRIAL SUMMARY

Study/Trial Title	Using Narrative Exposure Therapy to treat Violent Offenders with Post Traumatic Stress and Emotion Dysregulation: A single case study series.
Clinical Phase	
Study Design	Single Case Series
Study Participants	Up to 6 participants recruited from Lincolnshire Partnership Foundation Trust Community Forensic Team.
Eligibility Criteria	Over 18 years Can communicate and understand English independently, in a way that would meet the B2 reference level in the CEFR global scale Experiencing post-traumatic stress or diagnosed with PTSD Has difficulties regulating emotions assessed as in clinical assessment from the Community Forensic Team Have committed a violent offence which they have been charged with.
Planned Sample Size	Up to 6 participants
Study/Trial Duration	Treatment duration: not set, based on clinical need, however a maximum of 6 months treatment period will be offered per person. Follow up duration: N/A Total Study/Trial duration: 1.5 years
Objectives	Primary: To investigate the feasibility of Narrative Exposure Therapy in violent offenders To investigate the potential effectiveness of Narrative Exposure Therapy in reducing post-traumatic stress in violent offenders Secondary: to investigate the potential effectiveness of Narrative Exposure Therapy in reducing symptoms of emotion dysregulation in violent offenders
Outcome Measures	Primary: International Trauma Questionnaire Difficulties in Emotion Regulation Scale -16 CORE -10 Secondary: HR variability measure – Polar H10 band Autobiographical integration measure Semi - structured change interview
Data Analysis	Please provide a summary of the type of analysis/statistical techniques to be employed Visual analysis of outcome measures

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	Between phase comparison using TAU – U calculation Content analysis of change interviews

KEY WORDS

Trauma Interventions, Narrative Exposure Therapy, Offenders, Violent Offenders, Emotion regulation.

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LIST OF ABBREVIATIONS AND DEFINITIONS

AE	Adverse Event
CEFR	Common European Framework of Reference for Languages
CF	Consent Form
CI	Chief Investigator
CRF	Case Report Form
GCP	Good Clinical Practice
HRA	Health Research Authority
ICF	Informed Consent Form
ISF	Investigator Site File (This forms part of the TMF)
LPFT	Lincolnshire Partnership Foundation Trust
NET	Narrative Exposure Therapy
NHS R&D	National Health Service Research & Development
PI	Principal Investigator
PIS	Participant Information Sheet
PTS	Post Traumatic Stress
REC	Research Ethics Committee
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
TMF	Trial Master File
UoL	University of Lincoln

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STUDY/TRIAL MANAGEMENT

ROLE OF STUDY/TRIAL SPONSOR AND FUNDER

The sponsor of the Study/Trial is the University of Lincoln. The university has granted a research budget for the researcher to use for expenses that the research may incur.

The Chief Investigator has overall responsibility for the Study and shall oversee all Study management.

Co – Investigators will offer supervisory support and advice to the Chief Investigator, they will not play any part in the study procedure.

STUDY MANAGEMENT COMMITTEES

Study Steering/Management Group

The Study Steering/Management Group shall meet monthly to ensure all practical details of the Study are progressing well and working well and everyone within the Study/Trial understands them.

STUDY BACKGROUND and RATIONALE

Trauma, emotion regulation and offending

Individuals within the offending population have experienced more adverse childhood experiences (ACE's) and traumatic life events than those within the general population (Almeida & Pessoa, 2023), indicating that experiences of post-traumatic stress may be more prevalent within this group when compared to the prevalence in the general population. Despite this, diagnosis of Post Traumatic Stress Disorder often goes undiagnosed and untreated within the offending population (Facer-Irwin et. al., 2022).

Emotion Regulation is defined as the ability to inhibit and maintain emotional expressions (Bridges, Denham & Ganiban, 2004). ICD - 11 indicates for a diagnosis for Complex Post Traumatic Stress Disorder there should be difficulties in emotion regulation present (Larson, 2024). This is further evidenced by Cloitre et.al. (2012) who indicated that Adverse Childhood Experiences and prolonged trauma in childhood may lead to difficulties in emotion regulation. Thus, if levels of ACE's and traumatic life events are more prevalent in offending populations, this may indicate potential difficulties in emotion regulation.

Post traumatic stress and Heart Rate Variability (HRV)

Post Traumatic Stress is identified as a cluster of symptoms that are associated with the diagnosis of PTSD. These symptoms include intrusions such as flashbacks and nightmares, avoidance, changes in cognition and mood such as negative thoughts about self or the world and arousal and reactivity for example being easily startled or on edge (ICD, 2025). Despite the experience of post traumatic stress being common in offending populations, PTSD often goes undiagnosed.

HRV refers to the fluctuation of heart rate over a period and is used as a physiological marker of mental wellbeing. HRV reflects the balance of the sympathetic and parasympathetic systems held within the autonomic nervous system. An increase in anxiety is reflected in reduced HRV, which indicates an increase in heart rate meaning that the sympathetic and parasympathetic systems are in acting parsimoniously. The ICD-10 recognises increased arousal as a post traumatic stress symptom, indicating increases in anxiety are related to post traumatic stress, thus reduced HRV. Research has shown alterations in HRV among individuals with PTSD, specifically, PTSD has been associated with reduced HRV (Tan et. al.,2011), similar to the findings with anxiety. The reduced HRV observed in PTSD patients may be a physiological manifestation of this heightened stress state that is associated with post-traumatic stress. Thus, measuring HRV is a sufficient way of measuring distress associated with post - traumatic stress via physiological symptomology which is less subjective.

What is Narrative Exposure Therapy?

Narrative Exposure Therapy (NET) is a short-term specific trauma therapy recommended by the National Institute for Health and Care Excellence (NICE) for work with refugees. NET was developed based on experiences seen in refugees and victims of torture. The researchers found that developing a narrative

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timeline of the victim's trauma, helped reduce post-traumatic stress symptoms and increased hope (NET Institute, 2025). In NET, individuals talk through a chronological narrative timeline of their life experiences, with the aim to reconstruct fragmented trauma memories into coherent narrative memories that are contextualised in the time and space that they originally happened (NET Institute, 2025). This is achieved by tapping into the fear network, the cognitive, emotional and sensory bodily memories of the trauma and connecting these memories to the chronological time that they happened, allowing for processing of the trauma memory and a more coherent, less fragmented life story being formed (NET Institute, 2025). Patients are encouraged to relive the emotions felt by the memory whilst staying connected to the present thus reminding the patient that the feelings are because of the memory, making episodic links to "then" and "now" (NET Institute, 2025). Furthermore, NET also works on the process of habituation, which means exposing yourself to the trauma memory, not avoiding it. This allows individuals to change their beliefs about the trauma memory by learning that the anxiety they feel when exposed to the memory will reduce (Lord, 2023), thus they will habituate to the memory.

Previous Research in NET

NET has an increasing evidence base across various populations and has gained support in its treatment for CPTSD (Schauer, Neuner, & Elbert, 2011). NET has been shown to be potentially effective in reducing post-traumatic stress in various populations including refugees (Lely, Smid, Jongedijk, Knipscheer, & Kleber, 2019) women who have experienced Interpersonal Violence (Lane, 2020) and veterans (Hecker, Hermenau, Crombach, & Elbert, 2015). An adapted version of NET (FORNET) has been shown to be a superior treatment in improving PTSD, aggression and depression in child soldiers (Robjant et. al., 2019, Koebach et. al., 2021). Thus, research has indicated the use of NET may be appropriate for those who have experienced traumatic life events and have potentially committed violence within the past. There is little evidence supporting the use of non-adapted NET in adults who have offended, thus further research is needed to investigate whether NET would be helpful in this population.

NET has also been evidenced to have less attrition than other trauma therapies when working with individuals with complex trauma histories, and NET is seen as the superior treatment for these individuals (Mørkved, et al., 2014), this suggests that NET may be beneficial for those with complex trauma such as ACE's and interpersonal childhood trauma, which is often seen in offending populations.

Rationale for study

This research aims to inform the growing research base of using NET within various populations. The results of this research have implications for further research into using NET within this population, which could indicate other potential positive outcomes such as decreased reoffending and use of services, which would decrease burden on already overstretched services. Despite the lack of research into using Narrative Exposure Therapy within offending populations, the intervention is starting to be used in practice and therefore research into this area is important to inform evidence-based practice. Furthermore, a lot of treatment focus for offenders is on managing forensic risk and is not person centred, often leaving the individual feeling that what has happened to them is not important. Research suggests that post traumatic stress is a risk factor for violent behaviour (Facer-Irwin, et.al., 2023), thus indicating that a focus on trauma rather than risk may be beneficial for those who have committed violent offences in reducing risk but also improving mental wellbeing. Moreover, as NET encourages a complete view of a person's timeline, not just highlighting negative events but positive life events too, this minimises the emphasis on solely negative life experiences. This allows individuals to consider positives parts of their lives, rather than just negative life events and trauma, which is often a difficulty experienced in forensic populations due to the nature of

STUDY OBJECTIVES AND PURPOSE

PURPOSE

The purpose of this investigation is to understand whether NET is feasible to use within the population of violent offenders. We aim to investigate this by looking at its impact on experiences of post - traumatic stress and ability to regulate emotion. We also aim to look at participant experiences of NET, to inform

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whether this intervention is acceptable to use in this population and is accessible for them. This knowledge would inform further investigations into the potential effectiveness of NET within this population.

PRIMARY OBJECTIVE

To investigate whether NET is feasible to use un the population of violent offenders.

SECONDARY OBJECTIVE(S)

To identify whether NET can reduce experiences of Post Traumatic Stress in individuals who have committed a violent offence.

To identify whether NET can improve emotion regulation in individuals who have committed a violent offence.

OUTCOME MEASURES/ENDPOINTS

PRIMARY OUTCOME MEASURE/ENDPOINT

International Trauma Questionnaire (ITQ)

SECONDARY ENDPOINTS/OUTCOMES

Post Change Interview

Difficulties in Emotion Regulation Skills (DERS-16)

EXPLORATORY ENDPOINTS/OUTCOMES

Heart Rate Variability

Autobiographical Integration

TABLE OF ENDPOINTS/OUTCOMES

Objectives	**Outcome Measures**	**Timepoint(s) of evaluation of this outcome measure (if applicable)**
Primary Objectives	International Trauma Questionnaire	Weekly at each session
Secondary Objectives	Difficulties in Emotion Regulation Scale (DESR-16) Post change interview	Pre and Post Intervention Post intervention
Exploratory/Tertiary Objectives	Heart Rate Variability Autobiographical Integration	Weekly at each session Weekly at each session

STUDY/TRIAL DESIGN

The study will be a Single Case Study Series, with 4 participants who will act as their own comparison groups by completing measures at both baseline and intervention phases. Single case designs aim to make causal inferences by using participants as their own control, through the baseline and intervention phase, and replicating these phases over a period of time (Lobo, Moeyaert, Cunha, & Babik, 2017). As the intervention does not allow for replication of the baseline phase in a participant, due to it potentially making lasting change, this will be replicated through multiple participants. The study will also include change interviews post intervention, to evaluate participant experience of Narrative Exposure Therapy, looking at

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the feasibility of the intervention. This will inform whether the intervention is potentially suitable to be used in this context, adhering to the ADAPT framework (Moore et. al., 2021).

STUDY/TRIAL

The study will be conducted in the Community Forensic Team, in which the researcher will be delivering NET to the participants. The researcher has completed necessary training though the NET institute, to be qualified in delivering NET. This consisted of a two-day in-depth course on the theoretical underpinnings and practical steps to deliver NET. NET is also taught with the DClinPsy programme for which this research is funded, thus the researcher has sufficient training in NET as a therapy programme. Furthermore, the researcher will be supervised by a clinical psychologist in the Community Forensic Team who is qualified in NET to fidelity check the sessions and ensure adherence to the NET protocol.

The sessions will be video recorded on LPFT approved equipment, which will be stored on a trust laptop in a secure file. The videos will only be used for purposes of fidelity testing in supervision and transcribing sessions as part of the NET process. The transcriptions will also be stored in a secure file on a trust laptop. All outcome measures completed will be stored in the same manner, any paper copies will be destroyed. The participants will not be offered a set number of sessions, however, stopping rules will be considered, and if there is no change in the participants symptoms of post – traumatic stress following 20 sessions of NET, the intervention at that point will be stopped.

Study End

The study will end on the completion of intervention with up to 4 participants. The study will aim to be completed in approximately January 2027.

DATA ANALYSIS

Visual Analysis is the recommended method of analysis for single case designs (Kratochwill, et. al., 2010) The investigation will use visual analysis to determine the relationship between the independent variable and the outcome measures and thus evidence that the change in outcome measure results was down to the manipulation of the independent variable, indicating causal relation. In this case, this would be evidencing that the reduction in symptoms of post-traumatic stress and improvements in emotion regulation was due to Narrative Exposure Therapy. Visual analysis aims to establish this via demonstrating effect, a significant difference in the data pattern, in three separate stages (Kratochwill, et. al., 2010). Pre and post measures will be analysed using standardised regression coefficient, to compare baseline and post treatment scores.

Between – phase comparisons will be made using the TAU – U calculation to compare baseline and intervention phases, to ensure consistency of data patterns. Within – phase comparisons will be made by calculating the percentage of data within 15% of the mean, as per guidance if 85% of the data fall within the 15% then the data is said to be stable (Lobo, Moeyaert , Cunha, & Babik, 2017). The change interviews will be analysed via content analysis to identify and interpret themes that participants discussed regarding their experiences of Narrative Exposure Therapy. These themes will add valuable information into the feasibility of this intervention within this population.

STUDY SETTING

The study will be conducted in an NHS setting, in the premises of the Community Forensic Team at St Georges Road Hospital, Lincoln. This is a multiuse space shared by multiple mental health teams. On the site, we will have access to a private therapy room, which is allocated to the team, to hold the sessions, this room is bookable, and will not be disturbed, however is near staff areas should any support from other staff needed.

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SELECTION OF PARTICIPANTS

ELIGIBILITY CRITERIA

Inclusion Criteria

- 18 years old and over
- Experiencing Post–Traumatic Stress or have a diagnosis of PTSD or CPTSD.
- Can communicate and understand English independently, in a way that would meet the B2 reference level in the CEFR global scale. This is due to the language of the therapist and nature of the therapy being a narrative therapy in which the participant has to talk through narratives of their trauma.
- Has been convicted of a violent offence.

Exclusion Criteria

- Anyone who is presenting as acutely unwell, or struggling with active suicidal ideation, with plans and intent. Dut to the nature of the therapy as stated above, and exposure to memories of potentially traumatic life events, it would not be suitable to conduct the therapy with those presenting with active risk.

Sampling

Size of sample

The investigation will be a single case series, and as such a power calculation to determine the participant number is not appropriate. Instead, the present investigation plans to analyse patterns of change within the participants presentation, to evidence whether the intervention is potentially effective.

Single case designs aim to make causal inferences by using participants as their own control, through the baseline and intervention phase, and replicating these phases over a period of time (Lobo, Moeyaert, Cunha, & Babik, 2017). As the intervention does not allow for replication of the baseline phase in a participant, due to it potentially making lasting change, this will be replicated through multiple participants. Research indicates that four replication phases is highly recommended to establish causal references (Lobo, Moeyaert, Cunha, & Babik, 2017). Therefore, the present study will aim to recruit up to four participants.

Sampling technique

Participants will be recruited via opportunistic sampling from the Community Forensic Team as part of LPFT. The sample will be based on voluntary response, as individuals will volunteer to take part in this research as opposed to receiving therapy as usual, for example a person assessed by the qualified psychologist in the team as being suitable for NET, will be offered to take part in the investigation as opposed to receiving NET through the service. This will not impact the quality of care the person will receive, as the therapy will be the same as what they would receive through the service should they wish to access it, and the person will still be supported by the Community Forensic Team. Furthermore, if a person would like to access another therapeutic intervention, and not access NET, they can do this through the service, they can also access NET through the service should they not wish to take part in the investigation. Whilst this means that the sample may not be representative of the population that this study aims to investigate, as the investigation will be a naturalistic single case design generalisability will not be the primary aim of this investigation

RECRUITMENT

Participants will be patients recruited from the patient caseload in Community Forensic Team in Lincolnshire Partnership Foundation Trust. Participants will be living in the community residing across Lincolnshire. Participants will be assessed by a qualified Clinical Psychologist in the Community Forensic

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Team, via clinical interview to ensure suitability for the therapeutic intervention and are willing to take part in the study, the assessment will include collateral history taking, exploration of prominent symptoms, and checking whether the patient meets the inclusion criteria of the study. The participant will then be offered to take part in the investigation, if they agree they will be given the participant information sheet to sign. This information will not be stored as part of the participant data but will inform whether the patient is suitable to take part in the study. Participants will be offered to take part in this study via the clinical team in the Community Forensic Team and will then be assessed. Thus, participants will be recruited opportunistically providing they meet the criteria of the study. Participants assessed via clinical interview will be assessed with the inclusion and exclusion criteria in mind. Participants who do not meet the inclusion criteria will be offered psychological support and intervention through the Community Forensic Team, which may include NET, should they wish to access this.

Data will be stored as per the Lincolnshire Partnership Foundation Trust Data Security, Information and Records Management Policy (2024), in which it states data will be protected against unauthorised access; thus the data will be held by the researcher only in a protected file on a trust laptop. Data will also be stored in line with the University of Lincoln Records Management Policy (University of Lincoln, 2024) in which data will be accessible by authorised personnel only and will be held on the university OneDrive in a protected file. Furthermore, when the research is produced, the researcher will anonymise the participants data by using a pseudonym. Demographic details for the participants will be obtained via the clinical system Rio and again will be stored in the same secure manner as above. This data will be obtained to ensure the participants meet the inclusion criteria for the study and do not meet any of the exclusion criteria.

It will be explained to the potential participant that entry into the trial is entirely voluntary and that their treatment and care will not be affected by their decision. It will also be explained that they can withdraw at any time, but attempts will be made to avoid this occurrence. In the event of their withdrawal it will be explained that their data collected so far may not be erased in accordance with the University's Research Privacy Notice and information given in the Participant Information Sheet and we will seek consent to use the data in the final analyses where appropriate.

Participant Payment

Participants will not be paid to participate in the trial.

CONSENT

All participants shall provide written informed consent. The Informed Consent Form (ICF) will be signed and dated by the participant before they enter the Study.

The ICF will be signed and dated by the participant before they enter the Study.

The qualified Psychologist and field supervisor in the Community Forensic Team will initially offer for the participant to take part in the investigation, following clinical assessment. The researcher will then meet with the participant and will explain the details of the Study and provide a Participant Information Sheet (and any other Study related literature), ensuring that the participant has sufficient time to consider participating or not. Opportunity will be given to the participant to ask any questions they may have has concerning Study/Trial participation.

The process for obtaining participant informed consent will be in accordance with the REC guidance, and Good Clinical Practice (GCP), University of Lincoln guidance and any other regulatory requirements that might be introduced. The investigator or their nominee and the participant shall both sign and date the Informed Consent Form before the person can participate in the Study.

Informed consent will be collected from each participant before they undergo any Study interventions (including history taking* – if applicable*) related to the Study.

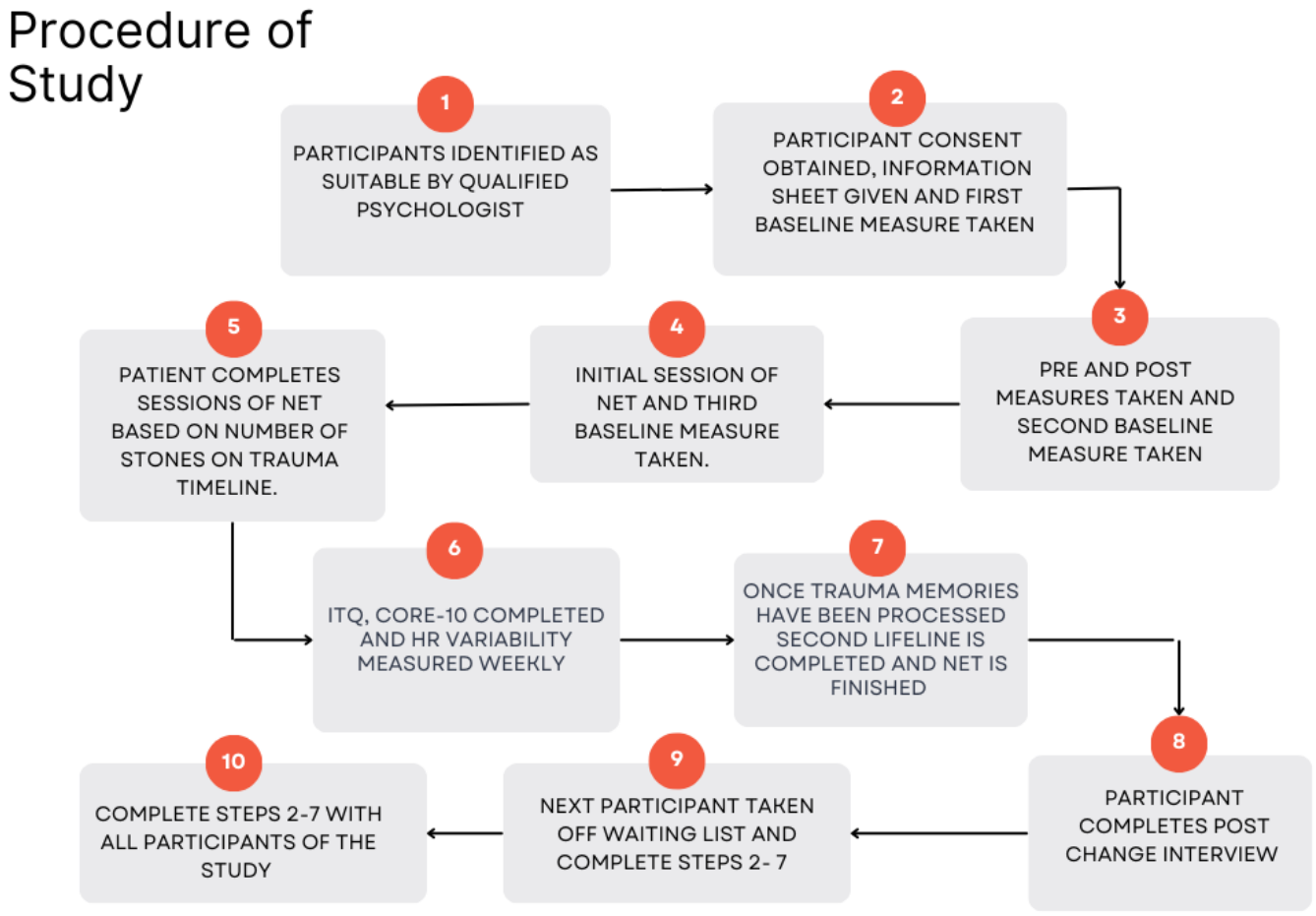
One copy of the ICF will be kept by the participant, one will be kept by the Investigator.

Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the trial, continuing consent will be obtained using an amended Consent form which will be signed by the participant.

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STUDY/PROCEDURES/REGIMEN

STUDY FLOWCHART



RANDOMISATION AND BLINDING

This study will not be randomised due to the nature of the study design.

STUDY REGIMEN

Measures

The investigation will involve delivering Narrative Exposure Therapy on a one to one basis with individuals. Narrative Exposure Therapy involves the patient creating a chronological timeline of their life, using flowers to represent positive experiences and stones to represent traumatic life experiences. Throughout the therapy the patient will be asked to narrate the experiences in order to process them, ensuring that they are contextualised to the time and place that they happened. In order to increase applicability to clinical practice, the number of sessions will not be set. As per recommended practice the session number will be based on the number of traumatic experiences depicted by stones on the lifeline. This is to ensure that those undertaking the investigation are receiving Narrative Exposure Therapy as usual.

The present investigation is a naturalistic single case series, thus measures will be repeated at intervals for each participant across the study. Measures will be administered by the researcher throughout

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the therapy. There will be a baseline phase of three weeks and an experimental phase of the therapy being delivered. Participants will act as their own control, limiting variables of participant and allowing for evaluation of intervention effectiveness. Measures will either be given weekly, or pre and post intervention. A post intervention semi structured change interview will also be conducted. The measures included in the present study will be:

Weekly measures:

- The International Trauma Questionnaire (ITQ) is a brief measure focussing on the core symptoms of Post Traumatic Stress Disorder (PTSD) and Complex Post Traumatic Stress Disorder (CPTSD) and was developed in line with the ICD-11 criteria for PTSD and CPTSD.
- Clinical Outcomes in Routine Evaluation-10 (CORE-10) is a short version of the CORE - OM and is a measure of psychological wellbeing, looking at the past week. It assessed various areas including anxiety, depression, trauma, physical problems, functioning and risk.
- Heart Rate Variability will be assessed using the Polar 10 Heart Rate Monitor.

Pre and Post measures:

- ABMICT (Lord, 2023) is an autobiographical Integration Measure which assessed the mechanisms of change in Narrative Exposure Therapy.
- The Difficulties in Emotion Regulation Scale -16 (DERS-16) is a shortened version of the DERS, designed to assess difficulties in emotion regulation.

A post intervention change interview will be conducted to assess feasibility of the intervention in this group. The interview will focus on the participants experiences of NET, including whether they found it helpful as an intervention, what parts of the therapy they found useful, how did they find engaging in the therapy and any potential issues that they experienced. The interviews will be transcribed and analysed by the researcher.

SCHEDULE OF PROCEDURES

Procedures	**Sessions (3 baseline sessions, no set number of NET sessions, 1 follow up)**						
	Screening	**Baseline measures**	**1st NET Session (Psychoeducation) and baseline measure**	**2nd NET Session (Timeline)**	**3rd NET session (memory processing) onwards**	**Final NET Session**	**Follow up**
Informed consent	X						
Demographics	X						
ITQ	X	X	X	X	X	X	
DERS -16		X				X	
CORE-10	X	X	X	X	X	X	
HR Variability Monitor	X	X	X	X	X	X	
Autobiographical Intergration					X	X	

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Measure - ABMICT (Lord, 2023)							
Post intervention Interview							X

WITHDRAWAL

Participants may be withdrawn from the trial either at their own request or at the discretion of the Investigator. The participants will be made aware that this will not affect their future care. Participants will be made aware (via the information sheet and consent form) that should they withdraw the data collected to date may not be erased in accordance with the University's Research Privacy Notice and information given in the Participant Information Sheet and may still be used in the final analysis. Participants who withdraw from the trail may be replaced if necessary to the completion of the study.

A consideration of this is that the participant may want to withdraw from the investigation but still want therapeutic intervention. This has been mitigated as the qualified psychologist within the LPFT community forensic team is trained in Narrative Exposure Therapy. This ensures that should participants withdraw from the investigation they will be able to access this intervention in the future. Moreover, participants will be able to access other therapeutic intervention within the Community Forensic Team, from the psychologists within the service, therefore should they decide they do not wish to engage in NET, they are able to access alternative therapeutic interventions within the team. Alternatively, should the participant need more imminent support or be in a crisis or vulnerable state, the Community Forensic Team duty worker will be able to liaise with the researcher and other services, such as Crisis services, to ensure the participant gets the urgent support needed.

ETHICAL AND REGULATORY CONSIDERATIONS

ASSESSMENT AND MANAGEMENT OF RISK

All participants involved in the study will be under the care of the community forensic team. Due to the nature of the intervention, it is understandable that there will be an emotional impact on the participant, due to them processing the trauma they have experienced. This may lead to experiences of distress by the participant. This will be managed within the session using psychological techniques to help manage the distress. The nature of NET means that the participant will be brought out of the trauma memory to a safe place and thus, this should help manage any distress caused by the processing of the memory. Furthermore, should the participant need more imminent support or be in a crisis or vulnerable state, the Community Forensic Team duty worker will be able to liaise with the researcher and other services, such as Crisis services, to ensure the participant gets the urgent support needed. The researcher will see the participants in the therapy room located in the building of the community forensic team. The researcher will notify the duty worker when seeing a participant and inform them of the session length. The researcher will also wear an alarm when seeing the participant.

There may be incidents where the participant needs to be withdrawn from the study, if they are not able to engage with the therapy or are in too much distress to continue. At this point, if the patient requires imminent crisis intervention, the researcher will contact the duty worker in the community forensic team who will liase with the appropriate services, as stated above. The researcher will consult with the sponsor and research team, including the chief investigator, field supervisor (psychologist in the community forensic team) and research supervisor on the decision to withdraw the participant before any decision is made. The researcher will also contact the participants named nurse in the team to discuss that the participant is not suitable to engage in the therapy. Should a decision to withdraw the participant be agreed by all the research team, the participant will be spoken to by the researcher who will explain the decision to withdraw them from the study, and explain should they wish to access the therapy again in the future they can through the psychologist in the community forensic team, or should they wish to take part in the study in the future when they feel more able to discuss their trauma they can, providing the investigation is still ongoing. They will then be offered a follow up session with the named nurse, any data collected from the participant will be destroyed.

Another consideration is the potential emotional impact of this study on the researcher, due to the fact that the researcher will be delivering the therapy, thus will be spending time exploring traumatic memories the

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participant has experienced. This will be mitigated by the researcher partaking in weekly supervision with a qualified psychologist who is trained in Narrative Exposure Therapy. Furthermore, should the researcher need any further emotional support, this can be sourced by the student services team at University of Lincoln.

Due to the nature of the investigation, all sessions with the participants will be video recorded for fidelity checks. This is to ensure that the researcher is adhering to the model of NET appropriately, the fidelity checks will be carried out with the clinical psychologist trained in NET, at the Community Forensic Team. In order to ensure confidentiality, no other person will have access to the video recording other than the researcher and clinical psychologist. Furthermore, in the participant information sheet, it will be explained that the sessions are recorded and the reasons for this, to ensure informed consent, and give the participant the right to withdraw due to this.

Information disclosed in the NET sessions will be confidential, and will not be shared to outside parties, other than the clinical psychologist in the team for supervisory purposes and the participants named nurse within the team. Session notes will be uploaded onto the clinical system RIO, however these will not go into detail about specific events. In the event that information is disclosed during the Study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly. Any safeguarding risks will be discussed and reported to safeguarding with the consent of the participant.

Individual participant medical information obtained as a result of this Study are considered confidential and disclosure to third parties is prohibited with the exceptions noted. Medical information may be given to the participant's medical team and all appropriate medical personnel responsible for the participant's welfare.

ADVERSE EVENTS

An adverse event (AE) is any untoward occurrence in a Study participant. An adverse event (AE) may therefore be any unfavourable and unintended sign, symptom, or disease that develops or worsens during the Study period.

An AE may include:

- Exacerbation of a chronic or intermittent pre-existing condition including either an increase in frequency or intensity of the condition.
- Significant worsening or exacerbation of the condition/indication under study.
- A new condition detected or diagnosed after Study therapy administration even though it may have been present prior to the start of the Study.
- Pre- or post-treatment events that occur as a result of protocol-mandated procedures (e.g., invasive protocol-defined procedures, modification of a patient's previous treatment regimen).

An AE does **not** include:

- Social or convenience hospital admissions where an untoward occurrence did not occur.
- Day to day fluctuations of pre-existing conditions present or detected at the start of the Study.
- The disorder being studied, or expected progression, signs, or symptoms of the disorder being studied unless more severe than expected for the patient's condition.

Adverse events of participation in this Study may be:

a. Increase in risk to self or others as a result of worsening mental health condition, to the point where the patient can no longer engage in the therapy.
b. Significant increase in post-traumatic stress symptomology, determined by the scores on the ITQ, to the point that the patient can no longer engage in the intervention.

Please include any known adverse effects of taking part in this type of activity described in the protocol

A serious adverse event (SAE) means any adverse event, adverse reaction, or unexpected adverse reaction, respectively, that:

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a. results in death,
b. is life-threatening,
c. requires hospitalisation or prolongation of existing hospitalisation,
d. results in persistent or significant disability or incapacity, or
e. consists of a congenital anomaly or birth defect

Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences.

NOTE: 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.

There are no serious adverse events anticipated with participating in this Study.

Participant reporting of adverse events

The Investigator will review all documentation (e.g., clinical notes or diagnostic reports) relative to the event being reported. The Investigator or clinician will then record all relevant information regarding an AE/SAE. All adverse events will be recorded and closely monitored until resolution, stabilisation, or until it has been shown that the Study intervention is not the cause. Reporting must be in accordance with CG-QMS SOP CG10 Adverse Events and Safety Reporting.

Participant removal from the Study due to adverse events

Any participant who experiences an adverse event may be withdrawn from the Study at the discretion of the Investigator. The participants will not be automatically withdrawn from the study in the incident of an adverse event, the participants will have space to discuss any adverse events and be offered any additional support needed alongside the study. The participant will be offered further support from the community forensic team, or any other services relevant to the participant need, for example crisis services or hospital admission. The patient will be offered immediate support if required from the duty officer at the community forensic team. Should the participant choose to withdraw or it be decided by the investigator to withdraw the participant, they will be offered the same support as stated previously.

ETHICS REVIEW AND COMPLIANCE

The Study shall not commence until the Study protocol, information sheets and consent forms have been reviewed and approved from a Research Ethics Committee and relevant NHS/Social Care permission is obtained

The sponsor will be responsible for deciding whether amendments are substantial and non-substantial in collaboration with the Chief Investigator.

Where an amendment is required to Study documentation that required REC approval, changes will not be implemented until REC approval and HRA categorisation is received. Where an amendment requires local approval, this shall be sought prior to the amendment be implemented at each site in accordance with the categorisation given on the HRA approval letter.

Should an amendment be required to eliminate an apparent immediate hazard to participants this may be implemented immediately and the REC/HRA and R&D will be notified as soon as possible.

Minor amendments for logistical or administrative purposes may be implemented immediately

Amendments will be logged on the Sponsor's Study/Trial Amendment Log and stored in the Trial Master/Site File(s).

Annual Progress Reports shall be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given – until the end of the Study/Trial.

A final report shall (where possible) be submitted to the REC within one year after the end of the Study/Trial.

If the Study is terminated prematurely the CI will notify the REC, including the reasons for premature termination.

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PEER REVIEW

The current study has been reviewed by staff at both Nottingham and Lincoln university, through panel presentations of the current study. Furthermore, the protocol of the study has been reviewed by Professor Thomas Schorder and Dr Stephanie Lane before submission to the ethics committee.

PUBLIC & PATIENT INVOLVEMENT

Service User involvement has been included in the designing of this study by seeking out feedback from members of the Service User and Carer Advisory Panel (SUCAP) on the Trent Clinical Doctorate programme. This feedback was sought out in the research proposal panel, where members of SUCAP were able to give feedback on this study proposal. The research proposal panel consisted of researchers, professors at the university and two SUCAP members. The feedback from the SUCAP members was then discussed with the study supervisor. The feedback influenced the design of the study by ensuring that we have time to stagger the participants of the study to reduce the risk of researcher burnout, as it was raised by SUCAP that it feels that there is a lot to do. Furthermore, the SUCAP members were asked to evaluate whether the study was useful as it stands, the SUCAP members agreed this would be a study they felt was useful and would meet the requirements of a doctoral level research study. The researcher will seek out service user feedback when necessary within the procedure of the investigation.

PROTOCOL COMPLIANCE

Accidental protocol deviations may occur at any time. Accidental protocol deviations will be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

Deviations from the protocol which are found to frequently recur are not acceptable, these will require immediate action and could potentially be classified as a serious breach.

Serious breaches will be recorded and reported in accordance with CG-QMS SOP CG11 Serious Breach

DATA PROTECTION AND PATIENT CONFIDENTIALITY

All Study/Trial staff and investigators will comply with the principles of the Data Protection Act (2018) in protecting the rights of Study/Trial participants with regards to the collection, storage, processing, and disclosure of personal information and will uphold the Act's/Regulations core principles.

Each participant will be assigned a Study/Trial identity number, for use on CRFs other trial documents and the electronic database.

Personal data, research data and the linking code will be stored in separate locations. When stored electronically, this will include using encrypted digital files within password protected folders and storage media. Personal information shall be stored separately to research data and will be kept secure and maintained.

Personal data will be stored for 1 year following the end of the Study/Trial, so that the Chief Investigator may provide participants with a summary of the research (should they wish to receive a copy).

Data generated as a result of this Study/Trial will be available for inspection on request by the participating physicians, the University of Lincoln representatives, the REC, local R&D Departments and the regulatory authorities.

INDEMNITY

Insurance and indemnity for trial participants and trial staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but trial participants may have recourse through the NHS complaints procedures.

The University of Lincoln as research Sponsor indemnifies its staff, research participants and research protocols with both public liability insurance and clinical trials insurance.

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ACCESS TO THE FINAL DATASET

The chief researcher and other contributors will have access to the final data set, which will be anonymised using a pseudonym for each participant. On completion of the study, the report will be uploaded to the university thesis repository.

DISSEMINATION POLICY

The data custodian will be the Chief Investigator on behalf of the University of Lincoln. The proposed time frame for the study is shown below in the Gannt Chart, the study, including write up of the results and submission will be completed by June 2027. Following this, one the thesis has been marked, dissemination of results will be carried out. This will include a copy of the results being forwarded to participants if required. Please see Gannt chart to illustrate research project timeline.

Step of research Project	**Year One (24 - 25)**			**Year Two (25 - 26)**			**Year Three (26 – 27)**		
	Sep-Dec	Jan - Apr	May - Aug	Sep-Dec	Jan-Apr	May - Aug	Sep - Dec	Jan - Apr	May-Aug
Development of Protocol									
Ethical Approval Requested and obtained									
Identification of participants									
Recruitment of participants to study									
Delivery of Intervention and Data Collection									
Data Analysis									
Write up of thesis									
Thesis Submission									
Dissemination of Results									

Authorship eligibility guidelines and any intended use of professional writers

The authorship of the final report will be the chief investigator, and the contributors listed above. There will be no professional writers used in the authorship of this report.

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