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Mixed-methods randomised study exploring the feasibility and acceptability of eye-movement desensitisation and reprocessing for improving the mental health of traumatised survivors of intensive care following hospital discharge: protocol

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ABSTRACT

Introduction Post-traumatic symptoms are common among patients discharged from intensive care units (ICUs), adversely affecting well-being, increasing healthcare utilisation and delaying return to work. Non-pharmacological approaches (eg, music, therapeutic touch and patient diaries) have been suggested as candidate interventions and trauma-focused psychological interventions have been endorsed by international bodies. Neither category of intervention is supported by definitive evidence of long-term clinical effectiveness in patients who have been critically ill. This study assesses the feasibility and acceptability of using eye-movement desensitisation and reprocessing (EMDR) to improve the mental health of ICU survivors.

Methods and analysis EMERALD is a multicentre, two-part consent, pilot feasibility study, recruiting discharged ICU survivors from three hospitals in the UK. We are gathering demographics and measuring post-traumatic symptoms, anxiety, depression and quality of life at baseline. Two months after discharge, participants are screened for symptoms of post-traumatic stress disorder (PTSD) using the Impact of Events Scale-Revised (IES-R). Patients with IES-R scores<22 continue in an observation arm for 12 month follow-up. IES-R scores≥22 indicate above-threshold PTSD symptoms and trigger invitation to consent for part B: a randomised controlled trial (RCT) of EMDR versus usual care, with 1:1 randomisation. The study assesses feasibility (recruitment, retention and intervention fidelity) and acceptability (through semistructured interviews), using a theoretical acceptability framework. Clinical outcomes (PTSD, anxiety, depression and quality of life) are collected at baseline, 2 and 12 months, informing power calculations for a definitive RCT, with quantitative and qualitative data convergence guiding RCT refinements.

Ethics and dissemination This study has undergone external expert peer review and is funded by the National Institute for Health and Care Research (grant number: NIHR302160). Ethical approval has been granted by South Central-Hampshire A Research Ethics Committee (IRAS number: 317291). Results will be disseminated through the lay media, social media, peer-reviewed publication and conference presentation.

Trial registration number NCT05591625.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Adheres to Medical Research Council guidance for evaluating complex healthcare interventions.
⇒ Mixed methods probe feasibility and acceptability enabling us to address cultural and contextual factors.
⇒ Consistent with existing clinical pathways and best practice guidance.
⇒ Not powered to detect between-group, clinically significant differences in post-traumatic symptoms.

INTRODUCTION

Background and rationale

Critically ill patients in intensive care units (ICUs) receive life-saving treatment, yet the burden of long-term physical, cognitive and mental health issues, collectively known as 'postintensive care syndrome', is significant.[1] Global ICU admissions are on the rise[2] and there is growing recognition of the need to address post-ICU survivorship as a defining challenge in 21st-century intensive care medicine.[3] Despite this, healthcare providers often overlook this phase,[4] resulting in multiple care transitions away from clinicians with an understanding of the underlying aetiology.[5]

Amidst the existential threat of critical illness, patients endure invasive treatments,

potent psychoactive drugs, a busy and confusing environment and limited communication, leading to normal acute anxiety responses.[6] However, a substantial proportion continue to suffer unpleasant psychological and somatic symptoms. Post-ICU discharge, 20%–25% experience symptoms similar to those of post-traumatic stress disorder (PTSD),[7] with over 30% and 40% experiencing depression[8] and anxiety,[9] respectively. These symptoms can be persistent,[10] co-occurring[11] and are associated with adverse outcomes including reduced quality of life, increased healthcare utilisation and delayed return to work.[9 12 13]

Despite this, access to clinical psychology remains under-represented in UK ICU recovery services.[14] Interventions like music therapy,[15] therapeutic touch[16] and patient diaries[17] have been explored, but systematic reviews reveal that definitive evidence of long-term effect is lacking. Trauma-focused psychological therapies, such as eye movement desensitisation and reprocessing (EMDR), offer some promise, with meta-analyses showing significant reductions in PTSD, anxiety and depression for treating a diverse range of traumatised populations.[18 19] EMDR is cost-effective[20] and is internationally recommended by major organisations for trauma-related symptoms.[21–24]

Recent investigations of EMDR's effectiveness in treating medical event-induced trauma, following cancer, stroke, cardiac events and multiple sclerosis have yielded promising but inconclusive findings.[25] Case studies with ICU survivors[26 27] and our own novel work with survivors of COVID-19-related critical illness[28] also show promise, underscoring the need for systematic evaluation in this population. However, definitive evidence of benefit is not available.

Objectives

The primary objective of the EMERALD study is to evaluate the feasibility and acceptability of an EMDR intervention for adult patients displaying traumatic stress symptoms following ICU discharge. These findings will guide the design of a robust, fully powered randomised controlled trial (RCT), aligning with Medical Research Council (MRC) guidance on evaluating complex medical interventions. Secondary clinical outcomes will inform the selection of a primary outcome for the larger trial and provide variance estimates for sample size calculations. Additionally, a light-touch observation arm will offer insights into the mental health trajectory of ICU survivors without traumatic stress symptoms 2 months after hospital discharge.

METHODS: PARTICIPANTS, INTERVENTIONS AND OUTCOMES

Design

This is a multicentre, mixed-methods, randomised controlled pilot feasibility study, with a two-part consent process and is reported using the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) reporting guidelines[29] (online supplemental file 1: Reporting checklist for protocol of a clinical trial). Initially, all participants enter part A, which is an observational study, where they complete a series of mental health questionnaires at baseline, 2 months and 12 months post-hospital discharge. If a participant shows symptoms of post-traumatic stress at the 2 month mark (scoring≥22 on the Impact Events Scale-Revised (IES-R)), they are invited to consider participating in part B, which is an interventional study of EMDR versus standard care. Those without post-traumatic stress symptoms at 2 months (≤21 on the IES-R) or those who decline participation in part B will be offered continuation of the observation arm. All participants from both part A and part B repeat the study assessments at 12 months posthospital discharge. See figure 1 for the participant timeline.

Study setting

The study is sponsored by the University Hospital Southampton National Health Service (NHS) Foundation Trust (FT). Recruitment will occur after adult patients are discharged from three adult NHS ICUs in the UK: University Hospital Southampton, Royal Bournemouth Hospital and Poole General Hospital. The intervention will be provided through NHS psychological therapy services in proximity to the study participants, specifically Southern Health NHS FT and Dorset Healthcare University NHS FT.

Part A participant recruitment

Recruitment is anticipated to occur between February 2023 and May 2024. Eligibility screening will target consecutive patients discharged from the participating ICUs. Research staff will approach eligible patients on hospital wards or within 2 months following hospital discharge, via a telephone call or email, providing a participant information sheet. Patients will be invited to complete an informed consent form (ICF), accessible electronically through Qualtrics on tablet devices provided by the trial team, via an emailed link or on paper to suit patient preference. This initial consent pertains to their participation in the observational study (part A), involving baseline data collection and psychometric assessments, with a follow-up evaluation at 2 months and 12 months following hospital discharge.

Eligibility criteria

Eligibility will be determined by hospital research nurses acting under delegated authority of the local Principal Investigator. Patients will be eligible for part A if they meet the following criteria:

- Survivor of an intensive care admission, who received level 3 care for >24 hours.
- Aged≥18 years.
- Capacity to provide informed consent.

Patients will be excluded if they meet any of the following criteria:

- Pre-existing cognitive impairment such as dementia.

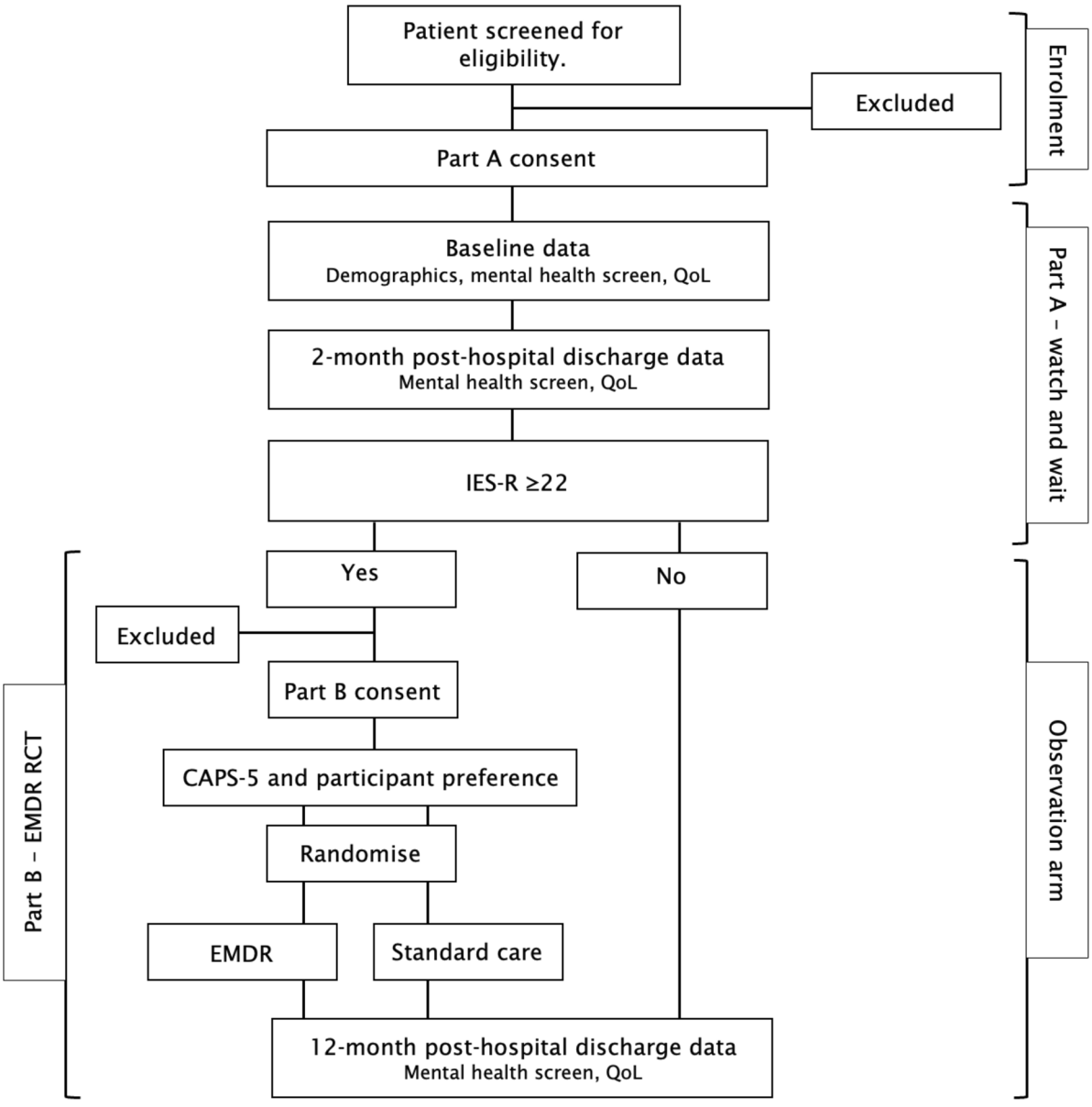

Figure 1 EMERALD participant timeline. CAPS-5, Clinician Administered PTSD Scale for DSM-5; EMDR, eye-movement desensitisation and reprocessing; IES-R, Impact of Events Scale-Revised; PTSD, post-traumatic stress disorder; QoL, quality of life; RCT, randomised controlled trial.

- Pre-existing diagnosis of psychosis.
- Not expected to survive beyond hospital discharge.
- Traumatic brain injury.

Baseline data collection

Research staff will collect demographic data, medical history and ICU admission history following consent. All participants will complete the Impact of Events Scale-Revised (IES-R), Patient Health Questionnaire-9 (PHQ-9), Generalised Anxiety Disorder 7 (GAD-7) and the Euroqol 5 Dimension 5 Level (EQ-5D-5L).

Two-month posthospital discharge assessment

All participants will be requested to repeat the IES-R, PHQ-9, GAD-7 and EQ-5D-5L. These patient-reported outcome measures can be completed electronically via an emailed link or by using paper versions sent with a prepaid return envelope.

The study team will review the IES-R responses. Participants with a total score≥22, indicative of post-traumatic stress symptoms, will be approached to consider participation in an EMDR versus usual care RCT (part B).

Participants without symptoms (IES-R≤21) or those not interested or unable to participate in the RCT will continue in the observational study, completing the 12 month follow-up assessment.

12-month follow-up assessment

Research staff will ask all participants, in both the observation group (part A only) and RCT (part A and part B), to repeat the IES-R, PHQ-9, GAD-7 and the EQ-5D-5L, at

Table 1 EMERALD study schedule of events

	Baseline	2 months postdischarge	3–9 months postdischarge	12 months postdischarge
Informed consent	X Part A	X* Part B		
Demographics	X			
IES-R	X	X		X
CAPS-5, CGI-S*		X*		X*
PHQ-9	X	X		X
GAD-7	X	X		X
EQ-5D-5L	X	X		X
EMDR intervention			X*	
IES-R, PHQ-9, GAD-7 (EMDR group only)				
Randomisation preference*		X*		
Process evaluation			X	X

X* for participants consenting to part B of the study only.
CAPS-5, Clinician Administered PTSD Scale for DSM-5; CGI-S, Clinical Global Impression of Illness Severity; EMDR, eye-movement desensitisation and reprocessing; EQ-5D-5L, EuroQol-5 Dimensions-5 Levels; GAD-7, Generalised Anxiety Disorder 7; IES-R, Impact of Events Scale-Revised; PHQ-9, Patient Health Questionnaire-9; PTSD, post-traumatic stress disorder; QoL, quality of life; RCT, randomised controlled trial.

12 months posthospital discharge. See table 1 for the full study schedule of events.

Part B participant recruitment

Participants scoring≥22 on the 2 month IES-R will receive a phone call or email from the study team, inviting them to consider consenting to part B, the EMDR versus usual care RCT. The part B PIS and ICF will be accessible electronically or via postal delivery. Those who consent to part B will first undergo a Clinician Administered PTSD Scale for Diagnostic and Statistical Manual of Mental Disorders, fifth edition (CAPS-5) assessment to evaluate PTSD symptoms and a Clinical Global Impression of Illness Severity (CGI-S) assessment with the Chief Investigator (CI). Additionally, participants will be asked to rate their preference for study arm strength using a Likert scale ranging from 0 to 10.

Randomisation

Consenting participants will be randomly assigned to either receive usual care or usual care combined with EMDR, utilising an internet-based system, following their CAPS-5 assessment. A researcher outside of the study team will undertake randomisation to ensure the CI remains blinded to study group allocation. Random allocation will occur in a 1:1 ratio, designating them to the control group (CG) for usual care or the intervention group (EMDR) for usual care plus EMDR.

Control group (CG)

Participants in the CG will receive the standard care package prescribed on hospital discharge, which may vary across study hospitals. Variations in standard care will be investigated through qualitative process evaluation and reported in the results manuscript. In case of adverse physical or psychological health conditions, they will access care through the usual available channels.

Intervention group (EMDR)

Participants randomised to the intervention group will receive the standard clinical care package following hospital discharge. Additionally, they will be referred to a participating adult NHS Psychological Therapies service using the established NHS–NHS referral system, identifying them as EMERALD participants. NHS Psychology teams will adhere to this research protocol for treatment. Any deviations from the protocol will be reported to the study team.

EMDR sessions, whether conducted via videoconference or face-to-face, will ideally commence within 4 weeks of referral and will be administered by trained EMDR therapists, who are supervised by a Consultant Clinical Psychologist. EMDR comprises eight phases, providing a structured treatment framework that supports consistency in session effects. The protocolised nature of EMDR facilitates training and replication in controlled studies. With participant and therapist agreement, some sessions will be recorded and assessed using the EMDR Fidelity Rating Scale (EFRS)[30] to allow granular reporting of the delivered intervention. The EMDR protocol, reported according to the TIDieR (template for intervention description and replication) guidelines, is available in online supplemental file 2. Sessions will last up to 60 min, and therapist-recorded adherence will track the number of sessions offered versus those completed. Participants

may receive up to 16 EMDR sessions based on the therapist's ongoing assessment of need.

Outcome measures

Primary outcome measures are feasibility and acceptability of trial process, to participants and staff.

Feasibility will be reported using the Consolidated Standards of Reporting Trials (CONSORT) statement as follows:

- Recruitment rate part A—we anticipate an average recruitment of 10 patients per month across the three participating sites. This is well above the median recruitment of 0.95 participants recruited per site per month, reported in a review of trials listed in the NIHR journals library (1997–2020).[31]
- Consent rate—number of patients recruited, expressed as a percentage of patients approached. Based on our previous work, we expect this to be greater than 30%.[28]
- Adherence will be determined by completion of ≥75% of planned EMDR sessions completed.
- Retention will be determined by ≥75% of participants completing the study follow-up assessment.

Acceptability will be determined by a qualitative process evaluation using semistructured interviews, and reported according to the Theoretical Framework of Acceptability.[32] In addition, we will assess fidelity to the EMDR delivery model using the EFRS. This will enable us to account for variability in intervention delivery. Safety will be determined by assignment of causality of serious events. Events attributable to trial procedures will be reviewed by trial management board, study sponsor and the Research Ethics Committee (REC) to determine ongoing feasibility.

In addition to sociodemographic characteristics, and medical history (including ICU admission data), secondary outcome measures will be collected at baseline, 2 months and 12 months posthospital discharge to capture possible clinical outcomes, mediators, moderators and covariates that may be included in the subsequent, definitive effectiveness trial. A detailed description of each of these measures is provided in online supplemental file 3. All data will be stored securely, pseudonymised by study number, on the Qualtrics electronic database. The secondary outcome measures include the following:

- Change in PTSD symptom severity using the Impact of Events Scale-Revised (IES-R)[33]
- Change in categorical diagnosis of PTSD using IES-R.
- Post-traumatic stress score using Clinician administered PTSD scale for DSM-5 (CAPS-5)[34]
- Clinical Global Impression-Severity scale (CGI-S).[35]
- Sensitivity analysis: to determine whether PTSD symptom burden identified by IES-R corresponds with those identified by CAPS-5.
- Anxiety: Generalised Anxiety Disorder-7 (GAD-7)[36]
- Depression: Patient Health Questionnaire-9 (PHQ-9)[37]
- Quality of life EuroQol Five Dimension-Five level scale (EQ5D-5L).[38]
- Clinical Global Impression of Improvement (CGI-I).[35]

Sample size

As this is a feasibility study, an a priori sample size calculation is not applicable. The findings will guide the sample size determination for a potential definitive RCT. Sample sizes of feasibility studies between 24 and 50 have been recommended to provide adequate estimate of SD for sample size calculation.[39 40]

To achieve this, a total of 160 patients will be enrolled in part A to assess feasibility adequately. Based on an expected incidence of 20%–25% post-ICU PTSD, we anticipate that around 40 patients will proceed to the part B RCT with an IES-R PTSD score≥22. The remaining 120 participants will continue in the observation arm, with a 12 month reassessment. Accounting for an estimated 25% mortality or loss to follow-up across all study arms, we anticipate approximately 30 participants completing the RCT and 90 participants completing the observation arm.

Data plan and analysis

Recruitment, retention and trial completion data will be visually represented in a CONSORT diagram. Quantitative outcome analysis, encompassing measures such as IES-R, CAPS-5, PHQ-9, GAD-7 and EQ5D-5L, will primarily be descriptive, emphasising estimation. Baseline measures and outcomes will be summarised using appropriate descriptive statistics, complete with associated CIs. The focus of interpretation will centre on the implications of these results for the feasibility of the main trial. Furthermore, we will conduct a confirmatory factor analysis of the DSM-5's four-factor PTSD diagnostic criteria, utilising data pooled from the CAPS-5 interviews.

Qualitative process evaluation

Qualitative description will be employed to construct a comprehensive overview of participants' and staff perceived experiences and the impact of the EMERALD study. This includes assessing the perceived burden associated with study participation and undertaking research activities. Qualitative interview data will serve to validate, elaborate on and broaden our understanding of the study's acceptability and feasibility, while also shedding light on potential factors that may hinder or enhance the EMERALD study. This information will be invaluable in refining the design of the subsequent RCT.

Method for obtaining and evaluating qualitative data

The process evaluation aligns with MRC guidance for complex intervention evaluations.[41] To efficiently capture implementation processes, we will employ Rapid Assessment Procedure Informed Clinical Ethnography.[42]

Stage 1: data collection involves selecting a purposive, diverse sample of trial participants and psychological therapists, minimising bias by adapting the sample to study needs. Participants will be invited for recorded telephone

or videoconference interviews at their convenience. We will use semistructured interviews guided by relevant objectives, incorporating patient and public involvement (PPI) recommendations, recent literature and a systematic review. See online supplemental material 4 for participant interview guide and psychological therapist interview guide. Sampling will continue until data saturation is reached, typically with 15–20 interviews.[43] The questions will be open-ended, and we will take field notes while digitally recording and transcribing interviews. The data will be reviewed by a senior researcher within the team to assess the need for further data collection.

Stage 2: the anonymised data set will be securely stored and analysed using NVivo qualitative data software. The analysis will follow the theoretical framework of acceptability, deductively coding content into seven constructs;[32] affective attitude, burden, intervention coherence, ethicality, opportunity costs, perceived effectiveness and self-efficacy.

Preliminary interpretation of emerging themes will be independently conducted, with consensus reached through discussion. Additional data collection will be considered if necessary. Agreed findings will be presented to a sample of study participants and PPI representatives to ensure validity and comprehensiveness.

Stage 3: will integrate qualitative findings with quantitative RCT data during the post-study interpretation phase. We will map data using a mixed-methods joint display,[44] and providing a holistic understanding of predetermined study objectives following established principles.

Safety considerations

Several systematic reviews have reported no adverse events attributable to EMDR. The intervention will be undertaken by suitably trained and experienced psychological therapists employed by the NHS. The service has an established and defined risk management and clinical governance structure. Online sessions will be compliant with Digital Approaches to therapy guidance from the British Psychological Society and NHS Digital. (This guidance contains expected standards relating to safeguarding, information governance, and GDPR.)

Participants who exhibit symptoms of intrusion/escalation will be treated according to the protocol unless it is determined that further treatment or escalation to emergency care may be necessary/indicated. If further treatment is required, the most appropriate course of action and referral pathway will be decided on a case-by-case basis by the psychology team. If deemed necessary, the CI will be unblinded to group allocation, to contribute to the safety discussion.

Monitoring and trial oversight

Day-to-day management will be the joint responsibility of the CI, Senior Project Co-Ordinator and Co-Investigators. This project is part of a PhD study undertaken by Andrew Bates (CI) with supervision by the co-investigators and authors.

Monitoring

The CI will facilitate monitoring by the local quality manager, REC review and provide access to source data as required. Following any monitoring, a report will be provided which will summarise the visit and documents, along with any fi/ndings. The CI will be responsible for ensuring that all findings are addressed appropriately. The study group will review all events in a timely manner. Additional monitoring will be scheduled where there is evidence of suspicion of non-compliance with the study protocol.

Patient and public involvement

PPI has shaped the study design, and this collaboration will persist throughout the project in the following ways:

Patient advisory group

An established PPI group attended advisory group meetings during project development. We are planning for meetings to occur every 6 months to review research findings, discuss key points, review press releases and dissemination outputs. Any study design amendments will be discussed and approved before submission.

Study management steering group

Two PPI members will serve as patient representatives in this decision-making group. They will oversee trial progress, review findings and outputs, approve project changes, and address arising issues, conflicts and risks in three meetings per year. One PPI group member will attend an intensive care conference to copresent study findings to clinical and academic leaders.

Patient groups and third sector

Study findings and dissemination outputs will be shared with and reviewed by patient groups and organisations such as ICU steps, EMDR UK, EMDR Europe and Anxiety UK. This ensures the inclusion of the patient perspective in the manuscript and keeps relevant stakeholders well informed.

Meetings will be conducted face-to-face with the option of videoconferencing for accessibility. A plain English research report, agenda and previous minutes will be circulated before each meeting, and meetings may be recorded with participant consent for later reference. Ongoing training tailored to individual needs will be provided for all participants, and the Public Involvement Lead for South Central Research Design Service will oversee ongoing PPI efforts.

ETHICS AND DISSEMIN§ATION

This study obtained prior approval from the South Central -Hampshire A Research Ethics Committee (REC) (22/SC/0410) before approaching participants, who will also review protocol modifications. Ethics approval covers all NHS trial sites, which were activated before enrolling patients.

The trial will adhere to the principles outlined in the 18th World Medical Assembly's recommendations from Helsinki 1964, as revised and recognised by governing laws and EU Directives. Consent to participate in the trial will be obtained only after providing a comprehensive explanation of treatment options, including conventional and widely accepted methods. The right of individuals to decline participation without specifying reasons will be respected.

Once a participant is enrolled in the trial, clinicians may administer alternative treatments beyond the protocol if they deem it in the participant's best interest, with the reasons duly documented. The participant will continue within the trial for follow-up and data analysis based on their allocated treatment option. Likewise, participants are free to withdraw from protocol treatment and trial follow-up at any time without providing reasons, without affecting their subsequent treatment.

The CI will inform the REC on study completion. In cases of premature termination, the CI will promptly notify the REC, including the reasons for the early conclusion.

Within 1 year following the study's conclusion, the CI will submit a final report containing results and any related publications or abstracts to the REC.

Dissemination activities will include but not be limited to:

- Publication in peer reviewed journals.
- Feedback to PPI study focus group.
- Feedback to study participants.
- Presentations to local clinical teams and managers and commissioners.
- Presentation at international conferences and within inter-disciplinary clinical networks.
- Public webinars, digital and social media.

DISCUSSION

The EMERALD study represents the second phase of our innovative exploration into whether EMDR can alleviate psychological distress after ICU discharge. Our mixed-methods approach, in line with MRC guidance for assessing complex healthcare interventions, enhances the study's robustness.[41] It allows us to capture cultural and contextual factors often missed in purely quantitative designs, thus improving the reliability of our findings and informing the design of our upcoming definitive RCT.

Building on the lessons from our prior study, CovEMERALD,[28] we have incorporated screening for psychological distress before entry into the RCT, aligning with recent review recommendations.[45] Adopting a 2 months posthospital discharge screening for PTSD follows both ICU rehabilitation[46] and PTSD treatment guidelines.[24] Furthermore, participants have the flexibility to choose either face-to-face or online intervention, without challenging participants' physical or psychological vulnerabilities.

A noteworthy aspect of this project is the strong collaboration between clinical academics specialising in intensive care, psychiatry and psychology, bolstered by our patient representatives, individuals with valuable lived experiences.

It is important to interpret clinical findings from this study cautiously, as it is not powered to detect clinically significant differences between groups. Nevertheless, these outcomes will inform future power calculations for the definitive RCT.

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Contributors AB and SR conceived the research idea. AB developed the theory, research plan, drafted the manuscript and is Chief Investigator for the study. HG acted as project manager during study set-up. All authors (AB, HG, SR, JH, NP, DSB, MG and RC) contributed to the study development and have reviewed, revised and approved this manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. Refer to the Methods section for further details.

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Supplemental file 1: Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	2 (link in text)
Protocol version	#3	Date and version identifier	n/a
Funding	#4	Sources and types of financial, material, and other support	1

Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1 and 13
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	n/a
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	n/a
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	n/a
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	2
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	2
Objectives	#7	Specific objectives or hypotheses	3
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg,	3

		superiority, equivalence, non-inferiority, exploratory)	
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	4
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	4
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8 and supplementary material
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	8
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	8 and supplementary material
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	8
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9

Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	see figure 1
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	10
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	5 and 8
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	8
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8

Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	11
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9, 10, 11
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	10,11
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	9
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	10

Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	na
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	na
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	12
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	12
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	11
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	12
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	12
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg,	12

		investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	5
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	na
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	9
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	15
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	10
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	11
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	12
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	12
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	12

Appendices

Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	3
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	na

Notes:

- 2b: 2 (link in text)
- 11a: 8 and supplementary material
- 11c: 8 and supplementary material
- 13: see figure 1 The SPIRIT Explanation and Elaboration paper is distributed under the terms of the Creative Commons Attribution License CC-BY-NC. This checklist was completed on 09. November 2023 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai

Supplementary file 2. EMDR treatment protocol reported according to TIDieR (Template for intervention description and replication)

Why: EMDR (Eye Movement Desensitization and Reprocessing) is hypothesised to alleviate post-traumatic symptoms among patients discharged from intensive care units (ICUs), by facilitating the adaptive processing of traumatic memories. The bilateral stimulation involved in EMDR is thought to assist in integrating memories of distressing experiences, potentially reducing the impact of trauma on mental health recovery. This study will investigate the feasibility and acceptability of delivering a randomised controlled trial (RCT) of EMDR following discharge from ICU.

What (material): No physical or informational materials were used during the intervention.

What (procedures): EMDR is a protocolised talking therapy which consists of 8 phases:

Phase 1: History taking and treatment planning: discuss participant history, with identification of traumatic events, develop a treatment plan, and assess participant's internal and external resources.

Phase 2: **Preparation:** establish a therapeutic alliance through explanation of EMDR process, discuss expectations, concerns, and questions, and equip participant with techniques to address disturbance that may arise.

Phase 3: **Assessment:** identify a target event, including associated memories, feelings, and images. Ask the participant to rate the associated disturbance, from zero to ten, using the Subjective Units of Distress scale, (SUD) and the Validity of Cognition (VOC) scale.

Phase 4: **Desensitisation:** focussing on the target event, the participant will be asked to perform side-to-side eye movements, tapping or sounds. This phase will be repeated until SUD reduces to zero or one.

Phase 5: **Installation:** Once SUD has reduced to zero-one, the participant will be guided to associate a positive belief, with the target event, until it feels consistently true.

Phase 6: **Body scan:** the participant is guided to hold both the target event and positive belief in mind, while scanning their bodily sensations from head to toe. If they identify lingering disturbance, they will repeat phase 4, until reprocessing is complete.

Phases 7 and 8 are delivered at the end of each session and are designed to ensure safety.

Phase 7: Closure: The psychological therapist assists the participant to return to a state of calm.

Phase 8: Re-evaluation: The psychological therapist and EMDR (Eye-movement desensitisation and reprocessing)

participants discuss recently processed memories and identify future target memories and directions for treatment.

Who provided: EMDR was delivered by trained, experienced psychological therapists employed by the United Kingdom (UK) National Health Service (NHS). The therapists are undergoing monthly peer to peer support and are being supervised by an EMDR Europe accredited Consultant Clinical Psychologist.

How (mode of delivery; individual or group): EMDR is delivered face-to-face or via Internet teleconference, according to participant preference.

Where: Face-to-face sessions will take place within the NHS psychological therapies clinic. Online teleconference will take place via Microsoft Teams™. Where participants are unable to attend either face-to-face or Internet sessions then a tablet with Internet dongle will be provided by the study team.

When and how much: Sessions will be delivered weekly, last for up to 60 minutes, and are provided individually. Participants will receive up to 16 sessions of EMDR.

Tailoring: The nature of trauma focused psychological therapies necessitates a personalised approach to the intervention. However representative sample of sessions will be recorded and reviewed by an expert practitioner for fidelity using the EMDR Fidelity rating scale.

How well (planned): Adherence to EMDR intervention will be expressed as a percentage of sessions offered against sessions completed. Psychological therapists will complete a diary card which will be made available to the study team at the end of the intervention.

Supplemental file 3. Secondary clinical outcome measures – description and timing

		Timepoint		
Measure	**Description**	**Baseline**	**Two-months post-hospital discharge**	**12-months post-hospital discharge**
Impact of Events Scale-Revised (IES-R) (1)	IES-R is a 22-question patient reported outcome measure (PROM) widely used to assess symptoms of PTSD in critical care research(2,3), recommended by critical care core outcome dataset developers(4–6) and the International Conference of Harmonisation of Outcome Measures(7). The 22 questions cover symptoms of intrusion, avoidance, and hyperarousal. Participants indicate how distressing the symptoms have been over the last 7 days. Symptom severity can be 0 (not at all), 1 (a little bit), 2 (moderately), 3 (quite a bit), 4 (extremely), giving a total scoring range of 0 to 88. A range of cut-offs for diagnosing PTSD have been identified in different populations. To maximise sensitivity, and minimise risk of leaving PTSD untreated, we will apply the lower cut-off of 22 and retrospectively conduct a sensitivity analysis against the CAPS-5.	X	X	X
Clinician Administered PTSD Scale for DSM-5 (CAPS-5)(8)	CAPS-5 is a structured diagnostic interview, considered the gold-standard assessment of PTSD symptoms. In addition to evaluating the 20 symptoms listed in the DSM-5, the questions focus on the onset and duration of these symptoms, the subjective distress experienced, how these symptoms impact an individual's social and occupational functioning, any improvement in symptoms since a prior CAPS assessment, the overall validity of the responses, the severity of PTSD as a whole, and the criteria for the dissociative subtype, which encompasses depersonalization and derealization. CAPS-5 assessment will be conducted face-to-face or over the phone, (according to participant preference) methods which deliver comparable results.		X (participants who have consented to part B only)	X (participants who have consented to part B only)
Clinical Global Impression-Severity scale (CGI-S)(9)	The CGI-S can be used to assess symptom severity and response to treatment. It requires a clinician to rate the severity of a patient's mental illness, on a seven-point scale ranging from; 1 – normal, not at all ill, 2 – borderline mentally ill, 3 – mildly ill, 4 – moderately ill, 5 – markedly ill, 6 – severely ill, 7 – among the most extremely ill patients.		X (participants who have consented to part B only)	X (participants who have consented to part B only)

Clinical Global Impression-Improvement scale (CGI-I)(9)	The CGI-I requires a clinician to assess degree of improvement since baseline, in a participant's symptoms, on a seven-point ranging from; 1-very much improved; 2-much improved; 3-minimally improved; 4-no change; 5-minimally worse; 6-much worse; 7-very much worse.		X (participants who have consented to part B only)	X (participants who have consented to part B only)
Patient Health Questionnaire (PHQ-9)(10)	Self-administred, vaildated tool assesses depressive symptom severity(10–12). Scores are calculated by assigning 0 for 'not at all, 1-'several days', 2 - 'more than half the days' or 3 – 'nearly every day' for responses to nine questions, giving a score in the range 0-27. PHQ-9 score of 0-4 demonstrates no - minimal depression severity. 5-9 = mild severity, 10-14 = moderate severity, 15-19 = moderately severe, 20-27 = severe.	X	X	X
Generalised Anxiety Disorder-7 (GAD-7)(13)	Seven-question, self-administered tool is validated to assess for anxiety symptom severity. Scores are calculated by assigning 0 for 'not at all, 1-'several days', 2 - 'more than half the days' or 3 – 'nearly every day' for responses to nine questions, giving a score in the range 0-21. GAD-7 scores of 5, 10 and 15 represent cut-offs for mild, moderate and severe anxiety respectively.	X	X	X
Health Related Quality of Life: Euroqual 5-level 5-Dimension (EQ-5D-5L)(14)	Comprises five quality-of-life dimensions; mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Participants report levels ranging from 'no problems' to 'extreme problems'.	X	X	X

EMERALD – Participant Interview Guide – Intervention group

Introduction and orientation:

- Thank you for agreeing to take part in this research and for being interviewed today.
- Cover logistics of video conference interview and outline the plan if technology issues are experienced.
- Discuss recording and how we will store and use the information in this interview.
- The interview will cover a range of questions about your experiences. There are no right or wrong answers. We are very interested in your experience of the study as it will help us to design better studies in the future.
- If at any time you do not wish to answer a question or are unsure how to answer, that's okay.
- If you have any opinions that may seem challenging or critical, then that is okay too.

- Do you have any questions about this?
- Can I start the recording now?

Semi-structured interview questions:

Introduction	Can you talk me through how you became aware of the EMERALD study and run through your involvement?
1. Affective Attitude: *How an individual feels about the intervention.*	I'd like you to think about how it felt taking part in the study. • How did you feel towards EMDR? What informed that feeling? • What did you like (or dislike) about EMDR? What were the best/worst parts? • Enquire about feelings of calmness, positivity, discomfort, anxiety, feelings of panic etc; may need to probe for more information with appropriate reflective listening.
2. Burden: *The amount of effort that was required to participate in the intervention*	I would like to discuss how much effort it took for you to undertake the EMERALD study – including any perceived difficulties or challenges? • Did you experience any practical problems – online or face-to-face? • Were there any consequences of receiving EMDR for you? • What was the impact on your daily life? • **Prompts:** may include cost, money, time commitment, or emotional burden • If not yet addressed: What about other members of your household or family? (How did they support you if needed?) • **Prompts:** help with internet access, use of technology, time, transport, financial
3. Ethicality: *The extent to which the intervention has good fit*	I would like to explore the ethics of EMDR, such as respect, competence, responsibility, and integrity. • Do you think there are any ethical issues with any aspect of taking part in the study?

with an individual's value system	• Can you describe any ethical implications to using EMDR in wider practice? • Was there anything we could have done to make the study fairer? • **Prompt:** In what ways do you think having EMDR fair or not fair?
***4.* Intervention Coherence:** *The extent to which the participant understands the intervention and how it works*	I notice that you attended XX sessions out of YY sessions arranged. I'd like to talk about your understanding of the EMDR. • Having had EMDR, how do you think it helped or (doesn't/didn't help) regarding your symptoms of post-traumatic stress? • How do you think it might work or not work? • How much did you feel that EMDR was the right approach? • What are your thoughts on the number of sessions? Do you think attending more (or fewer) sessions would change how effective it was?
***5.* Opportunity Cost:** *Experienced opportunity cost: The benefits, profits or values that were given up to engage in the intervention*	I'd like you to describe your feelings of the value and the potential costs of undertaking EMDR. • What were the pros and cons of EMDR? Was there anything that you particularly liked or disliked? • Was there anything that you had to give up so that you could have your EMDR? • Do you have any reservations that you would like to discuss?
***6.* Perceived Effectiveness:** *The extent to which the intervention is perceived to have achieved its intended purpose.*	• How effective do/did you think (engaging with) EMDR was? • How has EMDR affected the things that are important to you? • **Prompts:** What weren't you able to do prior to EMDR that was important to you? • Are you able to do this now? (work, home, social relationships) • In what ways do you feel better/worse, emotionally, or physically?
***7.* Self-efficacy:** *The participant's confidence that they can perform the behaviour(s) required to participate in the intervention*	• How confident were you that you could (safely) take part in the study +/- the EMDR? • How easy or difficult was it to stay engaged/concentrate for the whole session? • **Prompt:** did it stir up any unpleasant or pleasant emotions? • Do you think **you** had an ability to benefit? • How did you address any challenges that we have previously discussed?

Question:
When considering all the things you've spoken about, what would be your overall summary of taking part in EMERALD?

Is there anything that you think could be done better?
Is there anything else you'd like to tell us?

Thank you for giving me your time again today and thank you for taking part in our study.

EMERALD – Psychological therapist Interview Guide

Introduction and orientation

Semi-structured interview questions:

Introduction	Can you talk me through how you became aware of the EMERALD study and run through your involvement? I'd like you to consider the study group meetings, referrals, and delivery of the EMDR.
1. Affective Attitude: *How an individual feels about the intervention.*	How did it feel to be taking part in the study. **Prompts:** Emotionally, did you enjoy it? Enquire about anything that you found surprising, uncomfortable, or anxiety provoking; may need to probe for more information with appropriate reflective listening.
2. Burden: *The amount of effort that was required to participate in the intervention*	I would like to discuss how much effort you feel it took to undertake the EMERALD study – you perception – any difficulties or challenges? Did you experience any practical problems –online or face-to-face, burden of the additional workload? What was the impact on your working life – time commitment and emotional strain. **Prompt:** could include cost, money, time/workload, or emotional burden Did you experience any (other) burden(s) because of your involvement? **Prompt:** help with internet access, financial
3. Ethicality: *The extent to which the intervention has good fit with an individual's value system*	Do you think there are any ethical issues with any aspect of the study? What about the randomisation, do you think there are ethical issues some people getting or not getting EMDR when traumatised? **Prompt:** In what ways do you think having EMDR or not having EMDR is fair or not fair? Was there anything we could have done to make the study fairer?

4. **Intervention Coherence:** *The extent to which the participant understands the intervention and how it works*	What is your understanding of EMDR and how it may be applicable with these participants? What do think was the aim of the EMDR? Did it seem sensible to use for post-ICU traumatic stress? How might it work for these patients? Do you think attending more (or fewer) sessions would change how effective it was?
5. **Opportunity Cost:** *Experienced opportunity cost: The benefits, profits or values that were given up to engage in the intervention*	Could you describe your feelings of the value of undertaking EMDR? **Prompt:** do you think this was better or worse than alternatives, including the option of doing nothing? Do you have any reservations that you would like to discuss?
6. **Perceived Effectiveness:** *The extent to which the intervention is perceived to have achieved its intended purpose.*	Do you think that EMDR has been effective for your participants? **Prompt:** How do you feel it may have affected various aspects of their life? (work, home, social relationships) Do you think they feel better, emotionally, or physically?
7. **Self-efficacy:** *The participant's confidence that they can perform the behaviour(s) required to participate in the intervention*	How confident were you that you could deliver the study/EMDR as per the protocol? **Prompt:** did it stir up any unpleasant emotions? Do you think **you** were able to benefit? How did you address any challenges that we have previously discussed?

We are very near to the end of our interview today and I would like to hear about how you felt overall.

Question:
When considering all the things you've spoken about, what would be your overall summary of taking part in EMERALD?

Is there anything that you think could be done better?

Is there anything else you'd like to tell us?

Thank you for giving me your time again today and thank you for taking part in our study.