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Restore and Rebuild (R&R): a protocol for a phase two, randomised control trial to compare R&R as a treatment for moral injury-related mental health difficulties in UK military veterans to treatment as usual

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Restore and Rebuild (R&R): a protocol for a phase two, randomised control trial to compare R&R as a treatment for moral injury-related mental health difficulties in UK military veterans to treatment as usual

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Abstract

Background: Exposure to potentially morally injurious events (PMIEs) is increasingly recognised as a concern across a range of occupational groups, including UK military veterans. Moral injury-related mental health difficulties can be challenging for clinicians to treat and there is currently no validated treatment available for UK veterans. We developed Restore & Rebuild (R&R) as a treatment for UK veterans struggling with moral injury-related mental health difficulties. This trial aims to examine whether it is feasible to conduct a pilot randomised control trial (RCT) of R&R treatment compared to a treatment as usual (TAU) control group.

Methods: We will use a feasibility single blind, single site RCT design. The target population will be UK military veterans with moral injury-related mental health difficulties. We will recruit N=46 veteran patients who will be randomly allocated to R&R (n=23) or TAU (n=23). Patients randomised to R&R will receive the 20-session one-to-one treatment, delivered online. Veterans allocated to TAU, as there are currently no manualised treatments for moral injury-related mental health problems available, will receive the one-to-one treatment (online) typically provided to veterans who enter the mental health service for moral injury-related mental health difficulties. We will collect outcome measures of moral injury, post-traumatic stress disorder (PTSD), alcohol misuse, common mental disorders, and trauma memory at pre-treatment baseline (before randomisation), end of treatment, 12-weeks and 24-weeks post-treatment. The primary outcome will be the proportion of patients who screen positive for PTSD and moral injury-related distress post-treatment.

Discussion: This trial will establish whether R&R is feasible, well tolerated and beneficial treatment for veterans with moral injury-related mental health difficulties. If so, R&R may

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improve access to effective care for those who struggle following moral injury and reduce the associated negative consequences for veterans, their families and wider society.

Keywords: moral injury; trauma; treatment; codesign; intervention; guilt; shame; military

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Exposure to potentially morally injurious events (PMIEs) is increasingly recognised as a concern across a range of occupational groups, including military personnel, healthcare workers, journalists, and emergency services [1–4]. PMIEs include acts of commission, omission and betrayal [5–8]. An example of a commission PMIE in a military context could be using undue force to detain an enemy combatant; whereas an act of omission may be being unable to help civilians on deployment due to restrictive rules of engagement. Betrayal PMIEs can include perceptions of being supplied faulty/inadequate equipment for the deployment mission[9].

For some individuals, PMIE exposure can contribute towards debilitating negative changes in beliefs about oneself and others (e.g. 'I am a horrible person', 'other people don't care about me'), as well as intense feelings of guilt, shame, and anger [5,10,11]. 'Moral injury' is a term used to describe these profound cognitive and emotional changes that some individuals can experience after PMIE exposure which violate their moral or ethical code [10]. While moral injury is not a diagnosable mental health condition, experiencing moral injury is significantly associated with a range of poor mental health outcomes, including posttraumatic stress disorder (PTSD), depression, anxiety and suicidality [12,13].

Currently no validated treatment for moral injury-related mental health difficulties exists in a UK setting. This represents a considerable concern and a recent UK study found that clinical care teams report feeling uncertainty about how to best treat patients with moral injury, in part, due to there being no manualised treatment available [14]. As research in the field of moral injury expands, it is increasingly recognised that, while moral injury and PTSD can co-occur [15], individuals who struggle following moral injury may have a distinct symptom profile and specific treatment needs [10,16]. For example, military personnel who report life-threat trauma have been found to experience difficulties with flashbacks, exaggerated startle response and nightmares [17]; while those who struggle with moral injury

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may be more likely to report high levels of guilt, shame, anger, depression and interpersonal difficulties [11,18]. People with a moral injury may also experience a significant deterioration in their intrapersonal and interpersonal relationships [19,20]. Relationship difficulties, can in turn, reinforce problematic cognitive and behavioural changes such as social withdrawal, isolation and self-contempt associated with guilt, shame and anger [9,20,21]

It has been argued that existing treatments for PTSD may not fully address the distress experienced by individuals with moral injury [22,23]. Moreover, some authors consider that existing PTSD treatments, such as prolonged exposure (PE), could exacerbate symptoms of guilt and shame in cases of moral injury [22]. Similarly, studies of patients who received trauma-focused cognitive behavioural therapy (TF-CBT) have reported that receiving standardised treatment did not fully address their moral injury-related symptoms of shame or guilt [24].

In recent years, some treatments have been developed to better meet the needs of patients with moral injury, including Adaptive Disclosure [25,26] and the Impact of Killing (IOK; [27,28]). While these preliminary trials have shown promising results, the studies have been primarily restricted to samples of US military personnel/veterans. This presents several limitations. First, treatments such as IOK – which focuses on psychological difficulties experienced after killing – may not be beneficial or applicable to individuals who experience a wider range of PMIEs. Studies with UK military and non-military samples show that acts of commission (including injuring/killing others) are less prevalent than reported PMIE experiences of omission and betrayal [29–33]. It is also possible that both of these treatments, which were developed and tested in US military personnel/veterans, may not entirely fit the needs of those serving in a UK military context. The US and UK militaries have different rules of engagement while on deployment and have been found to have different experiences

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and reactions to trauma exposure [34]. Therefore, there is a need for a treatment that considers the needs and responses of UK veterans who are struggling with moral injury-related mental health difficulties.

To respond to this gap, Restore and Rebuild (R&R) was developed as a treatment for moral injury-related mental health difficulties. R&R was co-designed with international leading experts in the field of moral injury [35] as well as UK military veterans with lived experience of PMIE exposure and moral injury [24]. Pilot data indicates that the 20-session R&R treatment was acceptable and well tolerated by veteran patients who reported a significant reduction in symptoms post-treatment [36]. However, how R&R compares to existing trauma-focused treatment typically offered for patients with moral injury remains unclear.

Objectives

This trial aims to examine whether it is feasible to conduct a pilot randomised control trial (RCT) of R&R treatment compared to a treatment as usual (TAU) control group. Our target population are treatment seeking UK military veterans with moral injury-related mental health difficulties. Our primary objective is to examine if it is feasible to recruit, randomise, retain and follow up participants to either R&R or TAU.

Our secondary objectives are: i) to compare outcomes related to PTSD and moral injury at 3-months and 6-months post-treatment, compared to pre-treatment baseline in our target population of patients receiving R&R versus TAU patients; ii) to examine whether R&R is acceptable and tolerable to patients and those delivering the intervention to inform an integrated process evaluation; iv) to compare outcomes related to wellbeing and quality of life for the total population of patients randomised to R&R and TAU at 3-months and 6-months post-treatment.

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This protocol follows the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) reporting guidance (see Supplementary material 1 for SPIRIT checklist).

Trial design

To address these aims, this study will use a feasibility single blind, single site RCT design. The target population will be UK military veterans with moral injury-related mental health difficulties.

Eligible veterans will be identified during the patient's initial assessment for treatment at a UK wide veterans mental health charity, Combat Stress. We will recruit N=46 veteran patients who will be randomly allocated to R&R (n=23) or TAU (n=23). Veteran patients allocated to R&R will receive the 20-session one-to-one treatment, delivered online by a Combat Stress clinician. Veterans allocated to TAU, as there are no recommended manualised treatments for moral injury related mental health problems available at present, will receive the one-to-one treatment (online) typically provided to veterans who enter Combat Stress for moral injury-related mental health difficulties. Veteran patients will complete psychological outcome measures at pre-treatment baseline, end of treatment, 12-weeks post-treatment and 24-weeks post-treatment. Qualitative interviews will be conducted with R&R veteran patients to explore acceptability and feasibility. During this 27-month trial, participant recruitment and treatment will take place between July 2023 and December 2024.

Methods

Ethical approval

This study was reviewed and approved by King's College London Research Ethics Committee (HR/DP-22/23-36849).

Study setting

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The study setting is Combat Stress, a leading UK charity delivering trauma-focused care to military veterans across the UK.

Patient and Public Involvement (PPI)

R&R was co-designed using extensive input from UK veterans as well as leading international experts [36]. In the present study, an independent steering committee consisting of UK military veterans, military chaplains, clinicians, and leading international experts in the field of moral injury will provide patient and public input on study materials/procedures, monitor study progress, advise the investigators on scientific/management issues, and ensure no major deviations from the study protocol occur.

Eligibility criteria

Veteran patients. Eligible participants for both arms of the trial will be UK military veterans who have completed a clinical assessment at Combat Stress. Veterans must have been clinically assessed to have a military-attributable moral-injury related mental health difficulty. No limitations eligibility according to demographic characteristics (e.g. gender, age, rank) will be imposed. Moreover, we will not restrict participation by deployment location or military service role. Exclusion criteria are listed in Table 1.

[INSERT TABLE 1 HERE]

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Exclusion and inclusion criteria will be screened through review of patient notes following an initial clinical assessment at Combat Stress, as well as during screening call prior to informed consent. Any patients who do not meet study inclusion criteria will be referred to services that better meet their needs by the Combat Stress clinician.

Inclusion criteria for qualitative interview. To be eligible for a qualitative interview, the veteran patients must have completed (or dropped out of) the R&R treatment and provided written informed consent, including consent for audio-recording the interview.

Sample size

A power calculation is typically used to determine the sample size needed to detect an effect of a given size with a certain degree of confidence. However, as this is a pilot, exploratory, study a calculation has not been performed. Following a pragmatic approach and consistent with previous pilot studies of PTSD and complex PTSD, we aim to recruit n=23 individuals per arm (total sample = 46). This approach will enable us to answer our research questions and calculate a sample size for an adequately powered, full-scale future trial.

Recruitment

When entering Combat Stress' clinical service, all presenting veterans receive a comprehensive full clinical assessment by a member of the inter-disciplinary team (IDT). PMIE exposure and associated distress will initially be determined via clinician rating, as all veterans are asked to provide an overview of their exposure to trauma and related symptoms as part of this assessment. All cases are discussed at a weekly case IDT management meeting. The details of veterans who express symptoms of moral injury-related mental health difficulties, and deemed ready for therapy by the IDT, will be forwarded onto research team for review. Following review of the completed assessment, the research team will approach

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the veteran to book a screening call for the trial. During the screening call, the veteran will then be assessed by the research therapist to confirm that moral injury appears to be their main presenting difficulty. Eligible veterans who are interested in taking part in the trial will then be sent a study information pack, including an information sheet and consent form. Once written consent is received, the research team will invite the veteran to complete the pre-treatment baseline measures sent via secure email link. Following the completion of the wellbeing measures, veterans will be randomised into R&R or TAU. The research assistant will inform the Combat Stress clinical care team of the outcome so veterans in TAU, or who opted not to participate in the trial, can be offered the standard treatment.

Assignment of interventions: Allocation and blinding

Veteran patients will be randomly allocated to treatment group to minimize bias. Asymptotic maximal procedure will be used to randomly assign patients to treatment groups [37]. Randomised lists will be generated using an online, closed-source, tool (https://ctrandomization.cancer.gov/tool/) . Randomisation will be overseen by DL.

Interventions

R&R. R&R is a manualised, 20-session talking therapy [36]. Treatment is delivered one-to-one between therapist and patient, remotely via Microsoft Teams. Sessions are 60 minutes in length and occur weekly, however a 4-week break in sessions takes place between Sessions 19 and 20 (the final session). Following review of existing treatments and co-development with experts and veterans with moral injury [38], R&R was designed to include moral injury psychoeducation; discussion of the PMIE(s); exploration of post-event changes in beliefs and thought processes; support to adaptively re-write or update these; and an examination of core values and goals for the future. R&R includes in-session discussions with therapist, as well as written exercises, thought records and worksheets, completed both

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inside and outside of sessions by veteran patient. An outline of treatment sessions can be found in Figure 1.

[INSERT FIGURE 1 HERE]

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TAU. As there is a lack of validated manualised treatments for moral injury available at present, TAU will be the one-to-one treatment that would typically be provided to veterans who entered Combat Stress for treatment for moral injury-related mental health difficulties. TAU will consist of one-to-one trauma-focused therapy with a therapist from the broader Combat Stress clinical team, delivered online. TAU is expected to include elements of psychoeducation, symptom-management and therapy intervention; typically following a Cognitive Behavioural or Cognitive Processing Therapy model [39]. Details of the TAU intervention provided to all TAU-arm participants will be recorded (e.g. treatment given, number of sessions, etc).

Outcome measures

Wellbeing outcome measures. To analyse the impact of R&R versus TAU at reducing the severity of veteran patient moral injury-related mental health symptoms, several self-report measures will be collected from all veteran patients at various time points pre- and post-treatment (see Table 1).

The primary outcome measures will be the Moral Injury Outcome Scale [40], which measures symptoms of moral injury, and the International Trauma Questionnaire (ITQ) [41] which measures symptoms of PTSD and complex PTSD.

Secondary outcome measures will also include the Moral Injury Scale (MORIS) (Williamson et al., under review), which measures moral injury-related distress. Symptoms of PTSD will be measured using PTSD Checklist for DSM-5 (PCL-5) [42]. Patient Health Questionnaire (PHQ-9) [43] which will be used to measure symptoms of depression. The Dimensions of Anger Reactions scale (DAR-5) [44] will be used to measure anger and the Alcohol Use Disorders Identification Test (AUDIT) [45] will be used to measure alcohol usage. Social support will be measured using the Oslo Social Support Scale (OSSS-3) [46].

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The Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS) [47,48] will be used to measure general mental wellbeing. The Short Form Health Survey (SF-12) will be used to measure physical health outcomes [49]. Finally, a short measure of moral injury memory perspective will be utilised, adapted from Wells and Papageorgiou [50]. This measure will be used to record the veteran patients' trauma memory perspective and whether this viewpoint changes during treatment (Supplementary material 2).

Additional information and measures. Demographic information (e.g. age, gender, military branch, years of military service, etc) will be collected from veteran patients at baseline. Health economics information will also be collected (at baseline, end of treatment and 24-weeks post-treatment, see Table 2) to explore whether, over the last six months, the veteran patient's mental health has led to their: having had days off work; visits to Accident and Emergency (A&E) departments and/or hospital; visits to their general practitioner (GP); contact with the police; or use of mental health helplines (e.g. Samaritans). Treatment related data will be collected relating to the number of R&R and TAU sessions attended, the number and nature of any serious adverse events, the number of patients who dropped out after the first treatment session, and any patients who are lost to follow up. Serious adverse events will be defined according to the National Research Ethics Service Guidelines [51].

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Qualitative interviews. To gain an in-depth understanding of whether R&R is acceptable and well tolerated, up to 23 veteran patients will be invited to interview at the end of their treatment by a study researcher (VW). Any veterans who drop out of R&R treatment will also be approached and invited to interview to explore their experiences of treatment. Prior to interviews, veterans will be informed that their interviews will be anonymised with identifying information removed on transcription and their participation in the interview will not impact the care they receive from Combat Stress or other services.

The interview schedule (Supplementary Material 3) will be informed by the research aims, the wider moral injury literature, and previous qualitative studies of experiences of psychological treatment for moral injury [8,9,11,52,53]. Interviews will focus on veterans' experiences of accessing psychological treatment, their perceptions of being offered a novel treatment for moral injury and taking part in the RCT, their experience of receiving R&R, aspects of the R&R treatment that did/did not work well, the impact of R&R on their daily functioning and wellbeing, barriers and facilitators to treatment and perceptions of any outstanding support needs. Veteran patients who received TAU will not be interviewed as considerable evidence already exists regarding perceptions of existing psychological treatments for moral injury-related mental health difficulties [18,24,54]. Interviews will be conducted by telephone or MS teams and audio-recorded with patient consent. Interviews will be transcribed verbatim, with audio recordings destroyed following transcription.

Planned data analysis

Quantitative. STATA 17 will be used to analyse the data. Descriptive statistics will be calculated for baseline, follow up and change scores for outcome measures with paired t-tests used to test for significant changes in scores from baseline and between treatment groups (R&R vs TAU). Descriptive statistics will also be used to examine the treatment delivery

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information (e.g. number of sessions attended, drop out, etc.) to explore acceptability and feasibility. Should there be missing data, multiple imputation methods will be used.

Qualitative. Interviews with R&R veteran patients (N=23) will be analysed using thematic analysis [55]. Interview data will be preliminary coded using an inductive 'bottom up' approach. Researchers will familiarise themselves with the data by reading and re-reading the transcripts; they will generate early codes; search for and generate preliminary themes; then finalise superordinate themes. Credibility will be checked via analytic triangulation using reflective discussions with co-authors. A reflexive journal will be also kept [56] in order to note the influence of the researchers' views, expectations or assumptions, and experiences to prevent premature or biased interpretation of the data.

Data Management

We will use Qualtrics to securely collect self-report questionnaire assessments at baseline, session 19, post-treatment, and 12-weeks and 24- weeks post treatment. Following questionnaire completion, data will be stored on secure KCL servers. Each veteran patient will be assigned a unique ID, and all study data will be labelled with ID (not name). A document linking patient ID and personal details and contact information will be stored separately from other data, with access restricted to the research team directly involved in collecting data and delivering treatment. At the end of the trial, the linking document including personal/contact information will be deleted. Pseudonymised study databases will be examined, cleaned, locked and signed off by senior authors prior to securely sharing with the study statistician (DL). Once main trial analyses are complete and published, we plan to make a sufficiently anonymised version of the main study databases available on a public repository for use by other researchers.

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Adverse events reporting and harms

Protocols for managing any risk or safeguarding concerns will be followed, and any potential adverse events will be recorded and monitored in line with the study adverse events protocol and Combat Stress standard operating procedures. Potential adverse events will be recorded, logged and monitored by the study clinicians and senior authors, and serious adverse events will be reported to the study's independent steering committee and the director of Combat Stress.

Participant withdrawal or discontinuation

Veteran patients in both arms will be free to withdraw from the trial at any point, without giving a reason and without their legal rights or care being affected. The study team may also withdraw veteran patients if they consider their continuation to be harmful. The study team will review occurrences of adverse events, whether events are considered to be attributable to the trial and decide whether the veteran patient should be withdrawn. Non-identifiable data from veteran patients who have been withdrawn from the study will be used to assess trial feasibility. Patient engagement may be ceased based on adverse events. In the case of an adverse event, the clinician will notify the study team. The study team will review this information and evaluate whether the event could reasonably be attributed to the R&R or TAU intervention or participation in the trial. All instances of adverse events will be reviewed, whether or not they are considered to be attributable to the interventions (R&R vs TAU) or trial, and, based on this information, determine whether the participant should be withdrawn and/or if the trial should continue, be suspended or stopped.

Treatment fidelity

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The R&R intervention will be delivered by an experienced psychotherapist (AB) who has already been trained in R&R delivery. The therapist will be supervised by VA and DM for the duration of the study. A selection of treatment sessions will be audio-recorded and assessed for treatment integrity and fidelity.

Dissemination plans

We will share a summary of trial outcomes with veteran patients and disseminate the findings widely to reach a variety of stakeholders. For example, we will publish study outcomes in open access articles in journals to reach academic and clinical audiences; present findings at both national and international conferences; create tailored reports for policy makers and care providers; and share findings via our institutional website, newsletters, blogs and social media platforms.

Discussion

This trial aims to explore the feasibility and acceptability of delivering a targeted psychological therapy (R&R) to veterans presenting with moral injury-related mental health difficulties, compared to current usual treatment provision. If R&R is found to be feasible, well tolerated and beneficial, R&R may improve access to effective interventions for those who struggle following moral injury and reduce the associated negative consequences for veterans, their families and wider society.

Trial status

Participant recruitment and treatment is expected to begin in July 2023 and continue until December 2024.

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Table 1

Participant exclusion criteria

	Exclusion criteria
1	Not aged 18 years or more;
2	Unwilling or unable to provide written informed consent;
3	Do not have military-attributable moral injury-related mental health problems as determined by their clinician;
4	Have speech or hearing difficulties or serious cognitive impairment;
5	Actively self-harming or expressing significant suicidal ideation;
6	Have received trauma-focused individual therapy within last three months or have planned concurrent psychological therapy treatment;
7	Experiencing serious cognitive impairment, dissociative identity disorder, other severe mental health difficulty (e.g. severe psychotic disorder), or have current alcohol or drug use disorder requiring further support or treatment;
8	Currently experiencing significant life stressors that would impair the participant's ability to engage in therapy (e.g. homelessness);
9	Unwilling to complete R&R or TAU treatment sessions remotely;
10	Have previously participated in R&R treatment in the treatment pilot (Williamson et al., 2023).

Note. R&R = Restore & Rebuild. TAU = treatment as usual.

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Figure 1. Outline of R&R treatment sessions

Session 1-2	Resource building	Formulation and emotional regulation strategies concentrating on fostering self-compassion.
Session 3-8	Focusing on the event	Recounting the PMIE via narrative exposure, evaluating responses to the event and determining stuck points.
Session 9-12	Moving on from the event	Cognitive re-structuring of core beliefs about self as well as others through examination of key themes including power, control, and trust.
Session 13-18	Rebuilding connections	Overcoming shame through sharing of PMIE narrative. Developing values-based goals to help re-build a value-centred life and enhance connections with others. Review barriers to recovery. Incorporating self-compassion into daily life.
Session 19-20	Ending	Reviewing progress, maintaining gains and plans for future, signposting if further needs identified.

Note. PMIE = potentially morally injurious event.

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Table 2

Measures administered pre-, during and post-treatment

Measure	Baseline Pre-Treatment	Session 19	End of Treatment	12- weeks Post Treatment	24-weeks Post Treatment
MIOS	X	X	X	X	X
MORIS	X		X	X	X
PCL-5	X	X	X	X	X
ITQ	X		X	X	X
PHQ-9	X		X	X	X
DAR-5	X		X	X	X
AUDIT	X		X	X	X
OSSS-3	X		X	X	X
SWEMWBS	X		X	X	X
SF-12	X		X	X	X
MI Memory Perspective Measure	X		X	X	X
Health economics information	X		X		X

Note. MIOS = Moral Injury Outcome Scale. MORIS = Moral Injury Scale (MORIS). PCL-5 = PTSD Checklist for DSM-5 (PCL-5). ITQ = International Trauma Questionnaire (ITQ). PHQ-9 = Patient Health Questionnaire (PHQ9). DAR-5 = The Dimensions of Anger Reactions scale (DARS-5). AUDIT = Alcohol Use Disorders Identification Test (AUDIT). OSS-3 = Oslo Social Support Scale (OSSS-3). SWEMWBS = Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS). SF-12= Short Form Health Survey (SF-12). MI Memory Perspective Measure = measure of moral injury memory perspective, adapted from Wells and Papageorgiou [50].

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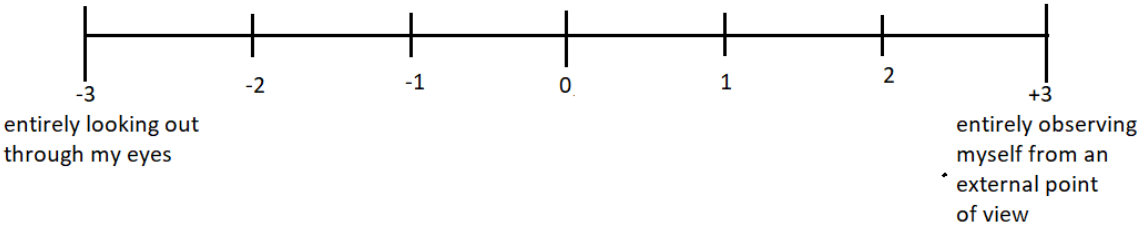
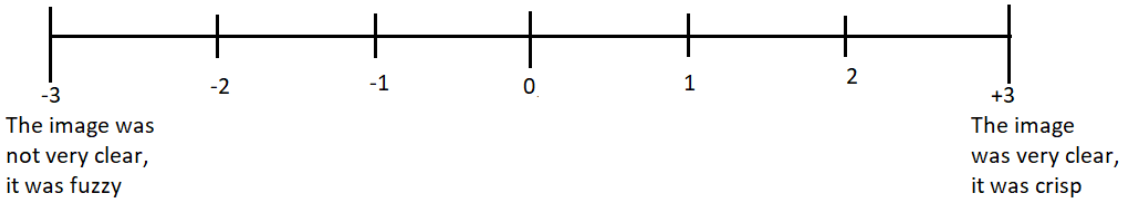
Supplementary Material 2 Trauma Memory Perspective

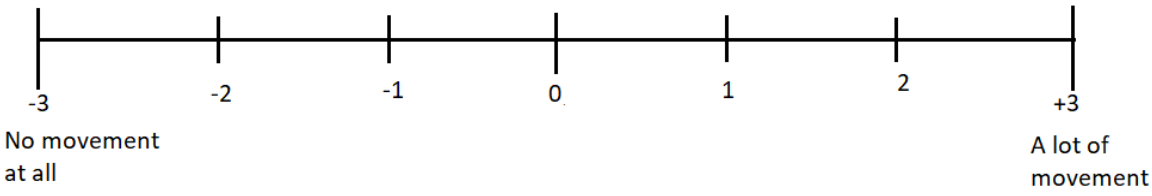
The event(s) or experience(s) related to moral injury which have brought you to this treatment will be stored as images in your memory. Thinking about the image that you have in your mind (you can close your eyes if this is helpful), is your predominant impression one of viewing the situation as if looking out through your eyes, observing the details of what is going on around you, or is your predominant impression one in which you are observing yourself, that is, as if you were outside of yourself, looking at yourself from an external point of view? Please look at this scale and give me a rating of your perspective.



How clear is the image of the event(s) in your mind?



How much movement do you remember in the event(s)?



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Supplementary Material 3

Indicative guide for in-depth interviews with R&R veteran patients

Topics to explore in the interview.

a. How have you found getting mental health treatment from Combat Stress so far?
    i. What made you want to seek help?
    ii. Were there any issues or concerns you were hoping treatment would help with?
b. How did you find being offered the R&R treatment?
    i. What did you hope to get out of taking part in this treatment?
    ii. Did you have any concerns at this stage?
    iii. Was there any more information you would have liked to have had?
c. How did you get on with the initial questionnaires and consent forms?
    i. Was there anything that you found difficult in filling in the questionnaires/consent forms?
    ii. Was there anything that could've been made easier for you here?
d. What did you think about the treatment being online/remote?
    i. How do you think this compares to a F2F treatment?
e. What aspects of treatment have gone well?
f. When do you find time to work through your homework?
    i. What things help you to engage? What things can get in the way?
g. Has the way that you think about the event(s) that brought you to therapy changed? If so, how?
h. Are there any changes to the treatment you think would be helpful?
    i. What features would you alter? Why?
i. How do you feel about managing your emotional/psychological difficulties having finished treatment?
    i. Has your knowledge or confidence changed since accessing treatment?
j. Has there been any change in your family life since taking up the treatment?
k. Have you become aware of any new sources of support as a result of being part of the treatment?

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l. How does this treatment compare to treatments you have had previously or other treatments you are aware of?
m. How do you feel about the number or length of sessions? Are there not enough or too many or just right?
n. In an ideal world, is there any other support or help you would've liked to receive?
    i. Could anything have been made easier for you/others to keep engaging with treatment?
o. Have you spoken with other people about the treatment you've received?
p. Is there anything we can do to make sure the treatments works well for other veterans in future?

Issues to explore in the interview for those who dropped out

q. At what stage did you begin to feel like treatment wasn't suitable for you?
r. Was there anything you didn't feel you were getting from the treatment that could be improved?
s. Did you have any particular needs you didn't feel were addressed by treatment?

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on 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_____
	2b	All items from the World Health Organization Trial Registration Data Set	_____
Protocol version	3	Date and version identifier	_1_____
Funding	4	Sources and types of financial, material, and other support	_1,2_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	_1,2_____
	5b	Name and contact information for the trial sponsor	_1_____
	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	_1,2_____
	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)	__8_____

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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	_4-7_
	6b	Explanation for choice of comparators	_6-7_
Objectives	7	Specific objectives or hypotheses	_6-7_
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	_7_
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	_7_
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)	_8,9_
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	_11-13_
	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)	_11_
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	_18_
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	_11-13_
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	_13-16_
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)	_10_

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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	_10_____
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	__11_____
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	_11_____
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	_11_____
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	__11_____
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	_____
Methods: Data collection, management, and analysis			
Data collection methods	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	__16,17_____
	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	__16_____

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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	_17_____
Statistical methods	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	_16,17_____
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	_NA_____
	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)	_17_____
Methods: Monitoring			
Data monitoring	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	_17_____
	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	_18_____
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	_18_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	_17-19_____
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	__7_____
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	_19_____

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Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	_9-10_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	_____
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	_17_____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	_1,2_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	_17_____
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	_12_____
Dissemination policy	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	_19_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	_2_____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	_____
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	_____
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	_____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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Restore and Rebuild (R&R): a protocol for a phase two, randomised control trial to compare R&R as a treatment for moral injury-related mental health difficulties in UK military veterans to treatment as usual

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Primary Subject Heading:	Mental health
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Keywords:	TRAUMA MANAGEMENT, MENTAL HEALTH, PSYCHIATRY

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Restore and Rebuild (R&R): a protocol for a phase two, randomised control trial to compare R&R as a treatment for moral injury-related mental health difficulties in UK military veterans to treatment as usual

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trustee for the funder of this project, the Forces in Mind Trust. Dr Leightley is a reservist in the UK Armed Forces. This work has been undertaken as part of his civilian employment.

For the purposes of open access, the author has applied a Creative Commons Attribution (CC BY) license to any Accepted Author Manuscript version arising from this submission.

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Abstract

Background: Exposure to potentially morally injurious events (PMIEs) is increasingly recognised as a concern across a range of occupational groups, including UK military veterans. Moral injury-related mental health difficulties can be challenging for clinicians to treat and there is currently no validated treatment available for UK veterans. We developed Restore & Rebuild (R&R) as a treatment for UK veterans struggling with moral injury-related mental health difficulties. This trial aims to examine whether it is feasible to conduct a pilot randomised control trial (RCT) of R&R treatment compared to a treatment as usual (TAU) control group.

Methods: We will use a feasibility single-blind, single-site RCT design. The target population will be UK military veterans with moral injury-related mental health difficulties. We will recruit N=46 veteran patients who will be randomly allocated to R&R (n=23) or TAU (n=23). Patients randomised to R&R will receive the 20-session one-to-one treatment, delivered online. Veterans allocated to TAU, as there are currently no manualised treatments for moral injury-related mental health problems available, will receive the one-to-one treatment (online) typically provided to veterans who enter the mental health service for moral injury-related mental health difficulties. We will collect outcome measures of moral injury, post-traumatic stress disorder (PTSD), alcohol misuse, common mental disorders, and trauma memory at pre-treatment baseline (before randomisation), end of treatment, 12-weeks and 24-weeks post-treatment. The primary outcome will be the proportion of patients who screen positive for PTSD and moral injury-related distress post-treatment.

Ethics & Dissemination: This trial will establish whether R&R is feasible, well tolerated, and beneficial treatment for veterans with moral injury-related mental health difficulties. If so, the results of the trial will be widely disseminated and R&R may improve access to

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effective care for those who struggle following moral injury and reduce the associated negative consequences for veterans, their families and wider society.

Keywords: moral injury; trauma; treatment; codesign; intervention; guilt; shame; military

Trial registration: ISRCTN99573523

Strengths and limitations

- A strength of this feasibility, single-blind study is that it will examine patient outcomes following treatment for moral injury, comparing treatment via R&R or TAU.
- A further strength is the use of mixed methods assessments, with patient outcomes explored via a range of psychometric measures post-treatment as well as qualitative interviews.
- An independent steering committee, consisting of veterans and key stakeholders, and will be drawn on for guidance throughout the trial.
- R&R and TAU will be delivered online, and it is possible that this may inadvertently exclude some individuals who have limited technological access or literacy.

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Exposure to potentially morally injurious events (PMIEs) is increasingly recognised as a concern across a range of occupational groups, including military personnel, healthcare workers, journalists, and emergency services [1–4]. PMIEs include acts of commission, omission, and betrayal [5–8]. An example of a commission PMIE in a military context could be using undue force to detain an enemy combatant; whereas an act of omission may be being unable to help civilians on deployment due to restrictive rules of engagement. Betrayal PMIEs can include perceptions of being supplied faulty/inadequate equipment for the deployment mission[9].

For some individuals, PMIE exposure can contribute towards debilitating negative changes in beliefs about oneself and others (e.g. 'I am a horrible person', 'other people don't care about me'), as well as intense feelings of guilt, shame, and anger [5,10,11]. 'Moral injury' is a term used to describe these profound cognitive and emotional changes that some individuals can experience after PMIE exposure which violate their moral or ethical code [10]. While moral injury is not a diagnosable mental health condition, experiencing moral injury is significantly associated with a range of poor mental health outcomes, including posttraumatic stress disorder (PTSD), depression, anxiety, and suicidality [12,13].

Currently no validated treatment for moral injury-related mental health difficulties exists in a UK setting. This represents a considerable concern and a recent UK study found that clinical care teams report feeling uncertainty about how to best treat patients with moral injury, in part, due to there being no manualised treatment available [14]. As research in the field of moral injury expands, it is increasingly recognised that, while moral injury and PTSD can co-occur [15], individuals who struggle following moral injury may have a distinct symptom profile and specific treatment needs [10,16]. For example, military personnel who report life-threat trauma have been found to experience difficulties with flashbacks, exaggerated startle response and nightmares [17]; while those who struggle with moral injury

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may be more likely to report high levels of guilt, shame, anger, depression, and interpersonal difficulties [11,18]. People with a moral injury may also experience a significant deterioration in their intrapersonal and interpersonal relationships [19,20]. Relationship difficulties, can in turn, reinforce problematic cognitive and behavioural changes such as social withdrawal, isolation and self-contempt associated with guilt, shame, and anger [9,20,21]

It has been argued that existing treatments for PTSD may not fully address the distress experienced by individuals with moral injury [22,23]. Moreover, some authors consider that existing PTSD treatments, such as prolonged exposure (PE), could exacerbate symptoms of guilt and shame in cases of moral injury [22]. Similarly, studies of patients who received trauma-focused cognitive behavioural therapy (TF-CBT) have reported that receiving standardised treatment did not fully address their moral injury-related symptoms of shame or guilt [24].

In recent years, some treatments have been developed to better meet the needs of patients with moral injury, including Adaptive Disclosure [25–27] and the Impact of Killing (IOK; [28,29]). While these preliminary trials have shown promising results, the studies have been primarily restricted to samples of US military personnel/veterans. This presents several limitations. Firstly, treatments such as IOK – which focuses on psychological difficulties experienced after killing – may not be beneficial or applicable to individuals who experience a wider range of PMIEs. Studies with UK military and non-military samples show that acts of commission (including injuring/killing others) are less prevalent than reported PMIE experiences of omission and betrayal [30–34]. Secondly it is also possible that both of these treatments, which were developed and tested in US military personnel/veterans, may not entirely fit the needs of those serving in a UK military context. The US and UK militaries have different rules of engagement while on deployment and have been found to have

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different experiences and reactions to trauma exposure [35]. Therefore, there is a need for a treatment that considers the needs and responses of UK veterans who are struggling with moral injury-related mental health difficulties.

To respond to this gap, Restore and Rebuild (R&R) was developed as a treatment for moral injury-related mental health difficulties. R&R was co-designed with international leading experts in the field of moral injury [36] as well as UK military veterans with lived experience of PMIE exposure and moral injury [24]. Data from a phase one, feasibility pilot study indicated that the 20-session R&R treatment was acceptable and well tolerated by veteran patients who also reported a significant reduction in symptoms post-treatment [37]. However, how R&R compares to existing trauma-focused treatment typically offered for patients with moral injury remains unclear.

Objectives

This trial aims to examine whether it is feasible to conduct a pilot randomised control trial (RCT) of R&R treatment compared to a treatment as usual (TAU) control group. Our target population are treatment seeking UK military veterans with moral injury-related mental health difficulties. Our primary objective is to examine if it is feasible to recruit, randomise, retain, and follow up participants to either R&R or TAU.

Our secondary objectives are: i) to compare outcomes related to PTSD and moral injury at 3-months and 6-months post-treatment, compared to pre-treatment baseline in our target population of patients receiving R&R versus TAU patients; ii) to examine whether R&R is acceptable and tolerable to patients and those delivering the intervention to inform an integrated process evaluation; iii) to compare outcomes related to wellbeing and quality of life for the total population of patients randomised to R&R and TAU at 3-months and 6-months post-treatment.

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This protocol follows the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) reporting guidance (see Supplementary Material 1 for SPIRIT checklist).

Trial design

To address these aims, this study will use a feasibility single-blind, single-site RCT design. The target population will be UK military veterans who served in either the British Army, Royal Navy or Air Force with moral injury-related mental health difficulties.

Eligible veterans will be identified during their initial assessment for treatment at a UK-wide veterans mental health charity, Combat Stress. We will recruit N=46 veteran patients who will be randomly allocated to R&R (n=23) or TAU (n=23). Veteran patients allocated to R&R will receive the 20-session one-to-one treatment, delivered online by a Combat Stress clinician. Veterans allocated to TAU, as there are no recommended manualised treatments for moral injury related mental health problems available at present, will receive the one-to-one treatment (online) typically provided to veterans who enter Combat Stress for moral injury-related mental health difficulties. Veteran patients will complete psychological outcome measures at pre-treatment baseline, end of treatment, 12-weeks post-treatment and 24-weeks post-treatment. Qualitative interviews will be conducted with R&R veteran patients to explore acceptability and feasibility. During this 27-month trial, participant recruitment and treatment will take place between July 2023 and December 2024.

Methods

Ethical approval

This study was reviewed and approved by King's College London Research Ethics Committee (HR/DP-22/23-36849).

Study setting

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The study setting is Combat Stress, a leading UK charity delivering trauma-focused care to military veterans across the UK.

Patient and Public Involvement (PPI)

R&R was co-designed using extensive input from UK veterans as well as leading international experts [37]. In the present study, an independent steering committee consisting of UK military veterans, military chaplains, clinicians, and leading international experts in the field of moral injury will provide patient and public input on study materials/procedures, monitor study progress, advise the investigators on scientific/management issues, and ensure no major deviations from the study protocol occur.

Eligibility criteria

Veteran patients. Eligible participants for both arms of the trial will be UK military veterans who have completed a clinical assessment at Combat Stress. Veterans must have been clinically assessed to have a military-attributable moral-injury related mental health difficulty. No limitations on eligibility according to demographic characteristics (e.g. gender, age, rank) will be imposed. Moreover, we will not restrict participation by deployment location or military role. Exclusion criteria are listed in Table 1.

[INSERT TABLE 1 HERE]

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Exclusion and inclusion criteria will be screened through review of patient notes following an initial clinical assessment at Combat Stress, as well as during a screening call prior to informed consent. Any patients who do not meet study inclusion criteria will be referred to services that better meet their needs by the Combat Stress clinician.

Inclusion criteria for qualitative interview. To be eligible for a qualitative interview, the veteran patients must have completed (or dropped out of) the R&R treatment and provided written informed consent, including consent for audio-recording the interview.

Sample size

A power calculation is typically used to determine the sample size needed to detect an effect of a given size with a certain degree of confidence. However, as this is a pilot, exploratory study a calculation has not been performed. Following a pragmatic approach and consistent with previous pilot studies of PTSD and complex PTSD [38–40], we aim to recruit n=23 individuals per arm (total sample = 46). This approach will enable us to answer our research questions and calculate a sample size for an adequately powered, full-scale future trial.

Recruitment

When entering Combat Stress' clinical service, all presenting veterans receive a comprehensive full clinical assessment by a member of the inter-disciplinary team (IDT). PMIE exposure and associated distress will initially be determined via clinician rating, as all veterans are asked to provide an overview of their exposure to trauma and related symptoms as part of this assessment. All cases are discussed at a weekly case IDT management meeting. The details of veterans who express symptoms of moral injury-related mental health difficulties, and deemed ready for therapy by the IDT, will be forwarded onto research team for review. Following review of the completed assessment, the research team will approach

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the veteran to book a screening call for the trial. During the screening call, the veteran will then be assessed by the research therapist to confirm that moral injury appears to be their main presenting difficulty. Eligible veterans who are interested in taking part in the trial will then be sent a study information pack, including an information sheet and consent form. Once written consent is received, the research team will invite the veteran to complete the pre-treatment baseline measures sent via secure email link. Following the completion of the wellbeing measures, veterans will be randomised into R&R or TAU. The research assistant will inform the Combat Stress clinical care team of the outcome so veterans in TAU, or who opted not to participate in the trial, can be offered the standard treatment.

Assignment of interventions: Allocation and blinding

Veteran patients will be randomly allocated to treatment group to minimize bias. Asymptotic maximal procedure will be used to randomly assign patients to treatment groups [41]. Randomised lists will be generated using an online, closed-source, tool (https://ctrandomization.cancer.gov/tool/). Randomisation will be overseen by DL.

Interventions

R&R. R&R is a manualised, 20-session talking therapy [37]. Treatment is delivered one-to-one between therapist and patient, remotely via Microsoft Teams. Sessions are 60 minutes in length and occur weekly, however a 4-week break in sessions takes place between Sessions 19 and 20 (the final session). Following review of existing treatments and co-development with experts and veterans with moral injury [42], R&R was designed to include moral injury psychoeducation; discussion of the PMIE(s); exploration of post-event changes in beliefs and thought processes; support to adaptively re-write or update these; and an examination of core values and goals for the future. R&R includes in-session discussions with therapist, as well as written exercises, thought records and worksheets, completed both

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inside and outside of sessions by veteran patient. An outline of treatment sessions can be found in Figure 1.

[INSERT FIGURE 1 HERE]

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TAU. Since there is a lack of validated manualised treatments for moral injury available at present, TAU will be the one-to-one treatment that would typically be provided to veterans who entered Combat Stress for treatment for moral injury-related mental health difficulties. TAU will consist of one-to-one trauma-focused therapy with a therapist from the broader Combat Stress clinical team, delivered online. TAU is expected to include elements of psychoeducation, symptom-management, and therapy intervention; typically following a Cognitive Behavioural or Cognitive Processing Therapy model [43]. Details of the TAU intervention provided to all TAU-arm participants will be recorded (e.g. treatment given, number of sessions, etc).

Outcome measures

Wellbeing outcome measures. To analyse the impact of R&R versus TAU at reducing the severity of veteran patient moral injury-related mental health symptoms, several self-report measures will be collected from all veteran patients at various time points pre- and post-treatment (see Table 1).

The primary outcome measures will be the Moral Injury Outcome Scale [44], which measures symptoms of moral injury, and the International Trauma Questionnaire (ITQ) [45] which measures symptoms of PTSD and complex PTSD.

Secondary outcome measures will also include the Moral Injury Scale (MORIS) (Williamson et al., under review), which measures moral injury-related distress. Symptoms of PTSD will be measured using PTSD Checklist for DSM-5 (PCL-5) [46]. The Patient Health Questionnaire (PHQ-9) [47] will be used to measure symptoms of depression. The Dimensions of Anger Reactions scale (DAR-5) [48] will be used to measure anger and the Alcohol Use Disorders Identification Test (AUDIT) [49] will be used to measure alcohol usage. Social support will be measured using the Oslo Social Support Scale (OSSS-3) [50].

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The Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS) [51,52] will be used to measure general mental wellbeing. The Short Form Health Survey (SF-12) will be used to measure physical health outcomes [53]. Finally, a short measure of moral injury memory perspective will be utilised, adapted from Wells and Papageorgiou [54]. This measure will be used to record the veteran patients' trauma memory perspective and whether this viewpoint changes during treatment (Supplementary Material 2).

Additional information and measures. Demographic information (e.g. age, gender, military branch, years of military service, etc) will be collected from veteran patients at baseline. Health economics information will also be collected (at baseline, end of treatment and 24-weeks post-treatment, see Table 2) to explore whether, over the last six months, the veteran patient's mental health has led to their: having had days off work; visits to Accident and Emergency (A&E) departments and/or hospital; visits to their general practitioner (GP); contact with the police; or use of mental health helplines (e.g. Samaritans). Treatment related data will be collected relating to the number of R&R and TAU sessions attended, the number and nature of any serious adverse events, the number of patients who dropped out after the first treatment session, and any patients who are lost to follow up. Serious adverse events will be defined according to the National Research Ethics Service Guidelines [55].

[INSERT TABLE 1 HERE]

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Qualitative interviews. To gain an in-depth understanding of whether R&R is acceptable and well tolerated, up to 23 veteran patients will be invited to interview at the end of their treatment by a study researcher (VW). Any veterans who drop out of R&R treatment will also be approached and invited to interview to explore their experiences of treatment. Prior to interviews, veterans will be informed that their interviews will be anonymised with identifying information removed on transcription and their participation in the interview will not impact the care they receive from Combat Stress or other services.

The interview schedule (Supplementary Material 3) will be informed by the research aims, the wider moral injury literature, and previous qualitative studies of experiences of psychological treatment for moral injury [8,9,11,56,57]. Interviews will focus on veterans' experiences of accessing psychological treatment, their perceptions of being offered a novel treatment for moral injury and taking part in the RCT, their experience of receiving R&R, aspects of the R&R treatment that did/did not work well, the impact of R&R on their daily functioning and wellbeing, barriers and facilitators to treatment and perceptions of any outstanding support needs. Veteran patients who received TAU will not be interviewed as considerable evidence already exists regarding perceptions of existing psychological treatments for moral injury-related mental health difficulties [18,24,58]. Interviews will be conducted by telephone or MS teams and audio-recorded with patient consent (Supplementary Material 4). Interviews will be transcribed verbatim, with audio recordings destroyed following transcription. It is beyond the scope of this study to share transcripts with participants for triangulation.

Planned data analysis

Quantitative. STATA 17 will be used to analyse the data. Descriptive statistics will be calculated for baseline, follow up and change scores for outcome measures with paired t-tests

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used to test for significant changes in scores from baseline and between treatment groups (R&R vs TAU). Descriptive statistics will also be used to examine the treatment delivery information (e.g. number of sessions attended, drop out, etc.) to explore acceptability and feasibility. Should there be missing data, multiple imputation methods will be used.

Qualitative. Interviews with R&R veteran patients (N=23) will be analysed using thematic analysis [59]. Interview data will be preliminary coded using an inductive 'bottom up' approach. Researchers will familiarise themselves with the data by reading and re-reading the transcripts; they will generate early codes; search for and generate preliminary themes; then finalise superordinate themes. Credibility will be checked via analytic triangulation using reflective discussions with co-authors. A reflexive journal will be also kept [60] in order to note the influence of the researchers' views, expectations or assumptions, and experiences to prevent premature or biased interpretation of the data.

Data Management

We will use Qualtrics to securely collect self-report questionnaire assessments at baseline, session 19, post-treatment, and 12-weeks and 24- weeks post treatment. Following questionnaire completion, data will be stored on secure KCL servers. Each veteran patient will be assigned a unique ID, and all study data will be labelled with ID (not name). A document linking patient ID and personal details and contact information will be stored separately from other data, with access restricted to the research team directly involved in collecting data and delivering treatment. At the end of the trial, the linking document including personal/contact information will be deleted. Pseudonymised study databases will be examined, cleaned, locked, and signed off by senior authors prior to securely sharing with the study statistician (DL). Once main trial analyses are complete and published, we plan to

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make a sufficiently anonymised version of the main study databases available on a public repository for use by other researchers.

Adverse events reporting and harms

Protocols for managing any risk or safeguarding concerns will be followed, and any potential adverse events will be recorded and monitored in line with the study adverse events protocol and Combat Stress standard operating procedures. Potential adverse events will be recorded, logged, and monitored by the study clinicians and senior authors, and serious adverse events will be reported to the study's independent steering committee and the director of Combat Stress.

Participant withdrawal or discontinuation

Veteran patients in both arms will be free to withdraw from the trial at any point, without giving a reason and without their legal rights or care being affected. The study team may also withdraw veteran patients if they consider their continuation to be harmful. The study team will review occurrences of adverse events, whether events are considered to be attributable to the trial and decide whether the veteran patient should be withdrawn. Non-identifiable data from veteran patients who have been withdrawn from the study will be used to assess trial feasibility. Patient engagement may be ceased based on adverse events. In the case of an adverse event, the clinician will notify the study team. The study team will review this information and evaluate whether the event could reasonably be attributed to the R&R or TAU intervention or participation in the trial. All instances of adverse events will be reviewed as to whether or not they are considered to be attributable to the interventions (R&R vs TAU) or trial, and, based on this information, determine whether the participant should be withdrawn and/or if the trial should continue, be suspended or stopped.

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Treatment fidelity

The R&R intervention will be delivered by an experienced psychotherapist (AB) who has already been trained in R&R delivery. The therapist will be supervised by VA and DM for the duration of the study. A selection of treatment sessions will be audio-recorded and assessed for treatment integrity and fidelity.

Ethics and Dissemination

We will share a summary of trial outcomes with veteran patients and disseminate the findings widely to reach a variety of stakeholders. For example, we will publish study outcomes in open access articles in journals to reach academic and clinical audiences; present findings at both national and international conferences; create tailored reports for policy makers and care providers; and share findings via our institutional website, newsletters, blogs, and social media platforms.

This trial, which was reviewed and approved by King's College London Research Ethics Committee, aims to explore the feasibility and acceptability of delivering a targeted psychological therapy (R&R) to veterans presenting with moral injury-related mental health difficulties, compared to current usual treatment provision. If R&R is found to be feasible, well tolerated, and beneficial, R&R may improve access to effective interventions for those who struggle following moral injury and reduce the associated negative consequences for veterans, their families and wider society.

Trial status

Participant recruitment and treatment is expected to begin in July 2023 and continue until December 2024.

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Table 1

Participant exclusion criteria

	Exclusion criteria
1	Not aged 18 years or more;
2	Unwilling or unable to provide written informed consent;
3	Do not have military-attributable moral injury-related mental health problems as determined by their clinician;
4	Have speech or hearing difficulties or serious cognitive impairment;
5	Actively self-harming or expressing significant suicidal ideation;
6	Have received trauma-focused individual therapy within last three months or have planned concurrent psychological therapy treatment;
7	Experiencing serious cognitive impairment, dissociative identity disorder, other severe mental health difficulty (e.g. severe psychotic disorder), or have current alcohol or drug use disorder requiring further support or treatment;
8	Currently experiencing significant life stressors that would impair the participant's ability to engage in therapy (e.g. homelessness);
9	Unwilling to complete R&R or TAU treatment sessions remotely;
10	Have previously participated in R&R treatment in the treatment pilot (Williamson et al., 2023).

Note. R&R = Restore & Rebuild. TAU = treatment as usual.

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Figure 1. Outline of R&R treatment sessions

Session 1-2	Resource building	Formulation and emotional regulation strategies concentrating on fostering self-compassion.
Session 3-8	Focusing on the event	Recounting the PMIE via narrative exposure, evaluating responses to the event and determining stuck points.
Session 9-12	Moving on from the event	Cognitive re-structuring of core beliefs about self as well as others through examination of key themes including power, control, and trust.
Session 13-18	Rebuilding connections	Overcoming shame through sharing of PMIE narrative. Developing values-based goals to help re-build a value-centred life and enhance connections with others. Review barriers to recovery. Incorporating self-compassion into daily life.
Session 19-20	Ending	Reviewing progress, maintaining gains and plans for future, signposting if further needs identified.

Note. PMIE = potentially morally injurious event.

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Table 2

Measures administered pre-, during and post-treatment

Measure	Baseline Pre-Treatment	Session 19	End of Treatment	12- weeks Post Treatment	24-weeks Post Treatment
MIOS	X	X	X	X	X
MORIS	X		X	X	X
PCL-5	X	X	X	X	X
ITQ	X		X	X	X
PHQ-9	X		X	X	X
DAR-5	X		X	X	X
AUDIT	X		X	X	X
OSSS-3	X		X	X	X
SWEMWBS	X		X	X	X
SF-12	X		X	X	X
MI Memory Perspective Measure	X		X	X	X
Health economics information	X		X		X

Note. MIOS = Moral Injury Outcome Scale. MORIS = Moral Injury Scale (MORIS). PCL-5 = PTSD Checklist for DSM-5 (PCL-5). ITQ = International Trauma Questionnaire (ITQ). PHQ-9 = Patient Health Questionnaire (PHQ9). DAR-5 = The Dimensions of Anger Reactions scale (DARS-5). AUDIT = Alcohol Use Disorders Identification Test (AUDIT). OSS-3 = Oslo Social Support Scale (OSSS-3). SWEMWBS = Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS). SF-12= Short Form Health Survey (SF-12). MI Memory Perspective Measure = measure of moral injury memory perspective, adapted from Wells and Papageorgiou [54].

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on 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_____
	2b	All items from the World Health Organization Trial Registration Data Set	_____
Protocol version	3	Date and version identifier	_1_____
Funding	4	Sources and types of financial, material, and other support	_1,2_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	_1,2_____
	5b	Name and contact information for the trial sponsor	_1_____
	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	_1,2_____
	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)	__8_____

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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	_4-7_
	6b	Explanation for choice of comparators	_6-7_
Objectives	7	Specific objectives or hypotheses	_6-7_
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	_7_
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	_7_
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)	_8,9_
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	_11-13_
	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)	_11_
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	_18_
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	_11-13_
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	_13-16_
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)	_10_

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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	_10_____
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	__11_____
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	_11_____
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	_11_____
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	__11_____
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	_____
Methods: Data collection, management, and analysis			
Data collection methods	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	__16,17_____
	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	__16_____

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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	_17_____
Statistical methods	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	_16,17_____
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	_NA_____
	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)	_17_____
Methods: Monitoring			
Data monitoring	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	_17_____
	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	_18_____
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	_18_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	_17-19_____
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	__7_____
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	_19_____

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Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	_9-10_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	_____
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	_17_____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	_1,2_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	_17_____
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	_12_____
Dissemination policy	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	_19_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	_2_____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	_____
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	_____
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	_____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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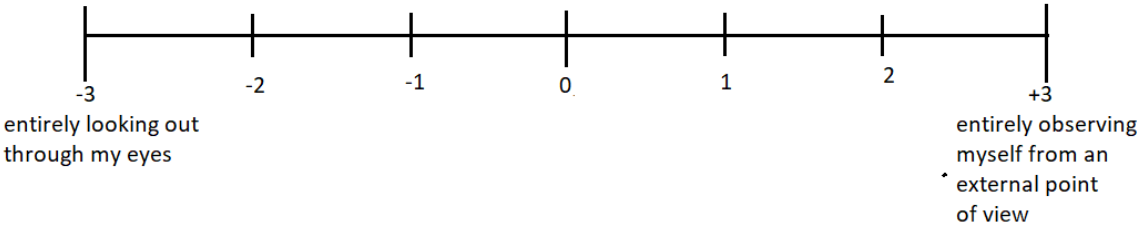
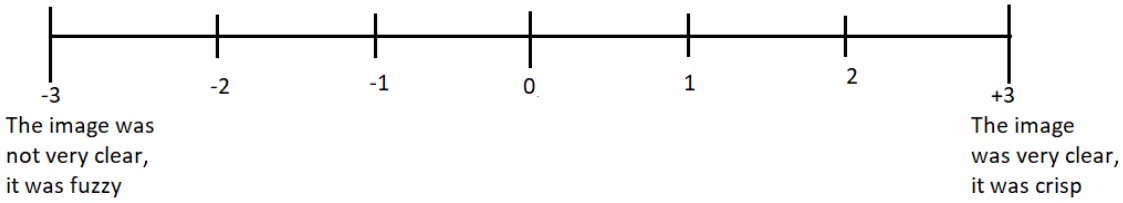
Supplementary Material 2 Trauma Memory Perspective

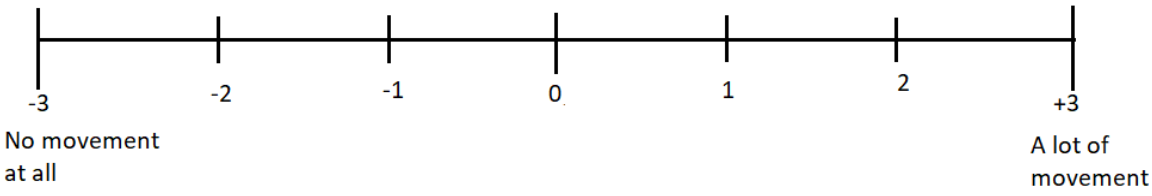
The event(s) or experience(s) related to moral injury which have brought you to this treatment will be stored as images in your memory. Thinking about the image that you have in your mind (you can close your eyes if this is helpful), is your predominant impression one of viewing the situation as if looking out through your eyes, observing the details of what is going on around you, or is your predominant impression one in which you are observing yourself, that is, as if you were outside of yourself, looking at yourself from an external point of view? Please look at this scale and give me a rating of your perspective.



How clear is the image of the event(s) in your mind?



How much movement do you remember in the event(s)?



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Supplementary Material 3

Indicative guide for in-depth interviews with R&R veteran patients

Topics to explore in the interview.

a. How have you found getting mental health treatment from Combat Stress so far?
    i. What made you want to seek help?
    ii. Were there any issues or concerns you were hoping treatment would help with?
b. How did you find being offered the R&R treatment?
    i. What did you hope to get out of taking part in this treatment?
    ii. Did you have any concerns at this stage?
    iii. Was there any more information you would have liked to have had?
c. How did you get on with the initial questionnaires and consent forms?
    i. Was there anything that you found difficult in filling in the questionnaires/consent forms?
    ii. Was there anything that could've been made easier for you here?
d. What did you think about the treatment being online/remote?
    i. How do you think this compares to a F2F treatment?
e. What aspects of treatment have gone well?
f. When do you find time to work through your homework?
    i. What things help you to engage? What things can get in the way?
g. Has the way that you think about the event(s) that brought you to therapy changed? If so, how?
h. Are there any changes to the treatment you think would be helpful?
    i. What features would you alter? Why?
i. How do you feel about managing your emotional/psychological difficulties having finished treatment?
    i. Has your knowledge or confidence changed since accessing treatment?
j. Has there been any change in your family life since taking up the treatment?
k. Have you become aware of any new sources of support as a result of being part of the treatment?

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l. How does this treatment compare to treatments you have had previously or other treatments you are aware of?
m. How do you feel about the number or length of sessions? Are there not enough or too many or just right?
n. In an ideal world, is there any other support or help you would've liked to receive?
    i. Could anything have been made easier for you/others to keep engaging with treatment?
o. Have you spoken with other people about the treatment you've received?
p. Is there anything we can do to make sure the treatments works well for other veterans in future?

Issues to explore in the interview for those who dropped out

q. At what stage did you begin to feel like treatment wasn't suitable for you?
r. Was there anything you didn't feel you were getting from the treatment that could be improved?
s. Did you have any particular needs you didn't feel were addressed by treatment?

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Supplementary Material 4 - Participant Consent Form

Patient Identification Number for this study:

Consent Form

Psychological treatment for moral injury in UK Armed Forces Veterans

Name of researcher: Dr Victoria Williamson & Prof Dominic Murphy

Please initial box

1. I confirm that I have read and understood the information sheet and privacy notice for the above study [Veteran Patient Information Sheet V3 07.07.23 & Patient Privacy Notice Statement 14.4.23 V1.] I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to stop participating at any time without giving any reason, without my care or legal rights being affected.	
3. I understand I have until 1 month after data collection to withdraw my data if I take part in a study assessment.	
4. I understand that all data will be stored to preserve confidentiality as described in the information sheet. I understand that nothing will be published in any research reports which could identify me.	
5. I consent to the processing of my personal information for the purposes explained to me in the Privacy Notice. I understand that such information will be handled in accordance with the terms of the General Data Protection Regulation (GDPR) and the UK Data Protection Act 2018	
6. I understand the information I provide Combat Stress for the purpose of this research study will be anonymised and shared with researchers at King's College London.	
7. I understand that the information I provide will be retained for a period of 10 years following completion of the study and then destroyed.	
8. I agree to my post-treatment interview with a researcher being audio recorded.	
9. I agree to my data from this interview being shared with a third-party transcriber who will have signed a confidentiality agreement.	
10. I agree to take part in the above study	

Name of Participant **Date** **Signature**

Thank you for agreeing to take part in this research

When completed, 1 for patient; 1 for researcher site file; 1 (original) to be kept in medical notes.

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