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Restore and Rebuild (R&R): a protocol for a phase 2, 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 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 and 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 controlled trial (RCT) of R&R treatment compared with 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 pretreatment 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 and 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 effective care for those who struggle following moral injury and reduce the associated negative consequences for veterans, their families and wider society.

Trial registration number ISRCTN99573523.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A strength of this feasibility, single-blind study is that it will examine patient outcomes following treatment for moral injury, comparing treatment via Restore and Rebuild (R&R) or treatment as usual (TAU).
⇒ A further strength is the use of mixed-methods assessments, with patient outcomes explored via a range of psychometric measures pre/post-treatment as well as qualitative interviews.
⇒ An independent steering committee, consisting of veterans and key stakeholders, 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.

INTRODUCTION

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 (eg, '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 post-traumatic 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 uncertain 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 considerable difficulties with flashbacks, exaggerated startle response and nightmares[7] while those who struggle with moral injury may be more likely to report high levels of guilt, shame, anger, depression and interpersonal difficulties.[11 17] People with a moral injury may also experience a significant deterioration in their intrapersonal and interpersonal relationships.[18 19] 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 19 20]

It has been argued that existing treatments for PTSD may not fully address the distress experienced by individuals with moral injury.[21 22] 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.[21] 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 responses or symptoms of shame or guilt.[23]

In recent years, some treatments have been developed to better meet the needs of patients with moral injury, including Adaptive Disclosure[24–26] 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] Second, 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 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 codesigned 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.[23] Data from a phase 1, 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.[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 controlled trial (RCT) of R&R treatment compared with a treatment-as-usual (TAU) control group. Our target population is 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 (1) to compare outcomes related to PTSD and moral injury at 3 months and 6 months post-treatment, compared with pretreatment baseline in our target population of patients receiving R&R versus TAU patients; (2) to examine whether R&R is acceptable and tolerable to patients and those delivering the intervention to inform an integrated process evaluation and (3) to compare outcomes related to well-being and quality of life for the total population of patients randomised to R&R and TAU at 3 months and 6 months post-treatment.

This protocol follows the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) reporting guidance (see online supplemental 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 pretreatment 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

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

Patient and public involvement

R&R was codesigned using extensive input from UK veterans as well as leading international experts.[36] In this 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 of 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 (eg, gender, age and rank) will be imposed. Moreover, we will not restrict participation by deployment location or military role. Exclusion criteria are listed in table 1.

Exclusion and inclusion criteria will be screened through a 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 the 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,[37–39] 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.

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 3 months or have planned concurrent psychological therapy treatment
7	Experiencing serious cognitive impairment, dissociative identity disorder, other severe mental health difficulty (eg, 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 (eg, 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*)

R&R, Restore and Rebuild; TAU, treatment as usual.

Recruitment

When entering Combat Stress clinical service, all presenting veterans receive a comprehensive full clinical assessment by a member of the interdisciplinary 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 are deemed ready for therapy by the IDT, will be forwarded to the research team for review. Following a review of the completed assessment, the research team will approach 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 pretreatment baseline measures sent via a secure email link. Following the completion of the well-being 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 those 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 minimise bias. Asymptotic maximal procedure will be used to randomly assign patients to treatment groups.[40] 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 min in length and occur weekly, however, a 4-week break in sessions takes place between sessions 19 and 20 (the final session). Following a review of existing treatments and codevelopment with experts and veterans with moral injury,[41] R&R was designed to include moral injury psychoeducation; discussion of the PMIE(s); exploration of postevent changes in beliefs and thought processes; support to adaptively rewrite or update these; and an examination of core values and goals for the future. R&R includes in-session discussions with a therapist, as well as written exercises, thought records and worksheets, completed both inside and outside of sessions by veteran patients. An outline of treatment sessions can be found in table 2.

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 CBT or cognitive processing therapy model.[42] Details of the TAU intervention provided to all TAU-arm participants will be recorded (eg, treatment given and number of sessions).

Outcome measures

Well-being outcome measures: To analyse the impact of R&R versus TAU on 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 pretreatment and post-treatment (see table 1).

The primary outcome measures will be the Moral Injury Outcome Scale,[18] which measures symptoms of moral injury, and the International Trauma Questionnaire[43] which measures symptoms of PTSD and complex PTSD.

Table 2 Outline of R&R treatment sessions

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

PMIE, potentially morally injurious event; R&R, Restore and Rebuild.

Table 3 Measures administered pretreatment, during and post-treatment

Measure	Baseline pretreatment	Session 19	End of treatment	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

MI Memory Perspective Measure=measure of MI memory perspective, adapted from Wells and Papageorgiou.[52]
AUDIT, Alcohol Use Disorders Identification Test; DAR-5, The Dimensions of Anger Reactions-5; ITQ, International Trauma Questionnaire ; MI, moral injury; MIOS, Moral Injury Outcome Scale; MORIS, Moral Injury Scale ; OSSS-3, Oslo Social Support Scale-3; PCL-5, PTSD Checklist for DSM-5 ; PHQ-9, Patient Health Questionnaire-9; SF-12, Short Form Health Survey ; SWEMWBS, Short Warwick-Edinburgh Mental Wellbeing Scale.

Secondary outcome measures will also include the Moral Injury Scale (Williamson *et al*, under review), which measures moral injury-related distress. Symptoms of PTSD will be measured using PTSD Checklist for The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5).[44] The Patient Health Questionnaire-9[45] will be used to measure symptoms of depression. The Dimensions of Anger Reactions scale-5[46] will be used to measure anger and the Alcohol Use Disorders Identification Test[47] will be used to measure alcohol usage. Social support will be measured using the Oslo Social Support Scale-3.[48] The Short Warwick-Edinburgh Mental Wellbeing Scale[49 50] will be used to measure general mental well-being. The Short Form Health Survey-12 will be used to measure physical health outcomes.[51] Finally, a short measure of moral injury memory perspective will be used, adapted from Wells and Papageorgiou.[52] This measure will be used to record the veteran patients' trauma memory perspective and whether this viewpoint changes during treatment (online supplemental material 2).

Additional information and measures: Demographic information (eg, age, gender, military branch and years of military service) 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 3) to explore whether, over the last 6 months, the veteran patient's mental health has led to their: having had days off work; visits to Accident and Emergency departments and/or hospital; visits to their general practitioner; contact with the police or use of mental health helplines (eg, 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.[53]

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 (online supplemental 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 17 54] 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 well-being, 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.[17 23 55] 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. It is beyond the scope of this study to share transcripts with participants for triangulation.

Planned data analysis

Quantitative: STATA V.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 information (eg, number of sessions attended and drop-out) 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.[56] 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; and then finalise superordinate themes. Credibility will be checked via analytical triangulation using reflective discussions with coauthors. A reflexive journal will be also kept[57] 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 the main trial analyses are completed 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.

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 all occurrences of adverse events, whether events are considered to be attributable to the trial, and decide whether the veteran patient should be withdrawn from the study. 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 cease.

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 with 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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Contributors All authors (VW, DM, NG, VA, AB, NB and DL) contributed to the design of the study. All coauthors (VW, DM, NG, VA, AB, NB and DL) contributed towards drafting the manuscript and reviewed and approved the manuscript prior to submission.

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

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