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R&R: A trial for moral injury related mental health difficulties

Submission date	Recruitment status	[X] Prospectively registered
16/05/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/06/2023	Ongoing	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/07/2026	Mental and Behavioural Disorders	

Plain English summary of protocol
Background and study aims
No manualised treatment for moral injury (MI) related mental disorders exists. International studies argue that existing trauma treatments can be unhelpful - even harmful – for people whose mental disorders are linked to MI. UK clinicians report uncertainty about how to treat MI. UK veterans struggling after potentially morally injurious events (PMIEs) report that routine treatments (e.g. trauma focused cognitive behavioural therapy [TF-CBT]) do not fully address their symptoms.

We designed the Restore & Rebuild (R&R) treatment to treat MI-related mental disorders. R&R has been successfully piloted & preliminary results show improvement in patient functioning, no drop out & no adverse events. Patient interviews show R&R is well tolerated. The time is now right to further explore the efficacy of R&R in a phase 2 exploratory trial.

We will examine if it is feasible & acceptable to pilot a randomised control trial (RCT) of R&R treatment compared to a treatment as usual (TAU) control group of UK veterans with MI-related mental disorders.

Who can participate?
UK military veterans who are experiencing mental health difficulties following a morally injurious event during military service are eligible to participate.

What does the study involve?
Taking part involves receiving a psychological therapy provided by a qualified psychotherapist at Combat Stress. This will be either the standard treatment for moral injury that Combat Stress currently delivers (TAU) or the new moral injury treatment (R&R) created by the research team. Before and after treatment patients will be invited to complete questionnaires about their thoughts and feelings and some will be invited to take part in an interview about their experiences of receiving treatment.

Where is the study run from?
The study is a joint project between King's College London and Combat Stress (UK). All treatment will be delivered at Combat Stress.

What are the possible benefits and risks of participating?
There is no direct intended benefit to taking part. In terms of possible risks, engaging in therapy can be emotionally challenging at times. However, it is normal to feel some distress during therapy and these emotional responses are often a necessary part of treatment and recovery. The therapists in both study arms will be trained and experienced in supporting individuals through these difficult thoughts and emotions and will work with patients to help them manage these feelings. If, at the end of the treatment, a patient feels that they are in need of further support, treatment referral and support options can be arranged.

When is the study starting and how long is it expected to run for?
May 2023 to June 2027

Who is funding the study?
The Forces in Mind Trust (UK)

Who is the main contact?
Dr Victoria Williamson, victoria.williamson@kcl.ac.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Study information

Scientific Title
R&R: A phase 2 randomised controlled trial for moral injury related mental health difficulties

Acronym
R&R RCT

Study objectives
We will examine if it is feasible and acceptable to pilot a randomised controlled trial (RCT) of Restore & Rebuild (R&R) treatment compared to treatment as usual (TAU) control group of UK veterans with moral injury related mental disorders. We will use a pilot RCT design to see if R&R treatment is feasible and well tolerated compared to TAU. We will examine recruitment and retention rates, if R&R is acceptable to patients, and compare psychological outcomes (e.g. PTSD, depression) between groups. Qualitative interviews will be conducted with patients to explore the acceptability of R&R.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/07/2023, King’s College London Research Ethics Committee (King’s College London Research Ethics Office, Franklin Wilkins Building, 5.9 Waterloo Bridge Wing, Waterloo Road,, London, SE1 9NH, United Kingdom; +44 20 7848 4020; rec@kcl.ac.uk), ref: HR/DP-22/23-36849

Approval pending, KCL Research Ethics Committee

Primary study design
Interventional

Study design
Single center single-blind randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Moral injury related mental health difficulties in UK military veterans.

Interventions
Intervention = Restore & Rebuild (R&R)
Control = treatment as usual (TAU).

R&R Treatment:
R&R is a manualised therapy treatment, there are 20 treatment sessions in total, delivered one-to-one between therapist and patient, delivered remotely via Microsoft Teams. Sessions are 60 minutes in length and are 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, this treatment was designed to include psycho-education, discussion of the morally injurious event(s), exploring the patient's changes in beliefs and thought processes and supporting the patient to helpfully re-write these, and exploring patient's values and goals for the future. The intervention will be delivered through in-session discussion with therapist, as well as written exercises, thought records and worksheets, completed both inside and outside of sessions by patient.

TAU Treatment:
Currently, there are no recommended manualised treatments for moral injury available at present. TAU will therefore be the one-to-one treatment that would typically be provided to veterans who entered Combat Stress for moral injury treatment. As such, following a full mental health assessment with a clinician at Combat Stress (standard practice for new patients), TAU will consist of one-to-one trauma-focused therapy with a therapist from the clinical team. This is likely to include elements of psych-oeducation, symptom-management and therapy intervention; typically following a Cognitive Behavioural or Cognitive Processing Therapy model. Details of the TAU intervention provided to all TAU participants will be recorded as part of the study.

Randomisation: Following informed consent, veteran patients will complete baseline questionnaire and will then be randomised by researchers to R&R or TAU.

R&R total duration = 20 sessions delivered once weekly.

TAU duration = patients assigned to TAU will be receiving the current gold standard one-to-one therapy sessions at Combat Stress. Typically, the TAU trauma-focused therapy being provided will be 12-24 sessions in length dependant on patient need and will taking place weekly. Number and type of sessions provided to patients in TAU will be recorded.

Follow-up = 3 months and 6 months post-treatment for both study arms.

Intervention Type
Behavioural

Primary outcome(s)
1. PTSD will be assessed via PCL-5 (Weathers et al., 2013) at baseline and 3-months post-treatment
2. Moral Injury-related Distress via MIOS (Litz et al., 2022) and MORIS (Williamson et al., under review) at baseline and 3-months post-treatment

Key secondary outcome(s)
Measures will be administered at baseline, 3- months and 6- months post-treatment.
1. Complex PTSD measured via International Trauma Questionnaire (ITQ).
2. The Patient Health Questionnaire (PHQ9) to measure symptoms of depression.
3. The Dimensions of Anger Reactions scale (DARS-5) used to measure anger.
4. Alcohol Use Disorders Identification Test (AUDIT) to measure alcohol usage.
5. The Oslo Social Support Scale (OSSS-3) to measure perceived social support.
6. The Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS) to measure mental wellbeing.
7. The SF-12 to measure physical health.
8. A short measure of moral injury memory perspective will be included, adapted from Wells and Papageorgiou (1995).

Completion date
01/06/2027

Eligibility

Key inclusion criteria
Veteran patients: The veteran must demonstrate presence of a military-attributable moral-injury related mental health difficulty confirmed via clinician assessment. Veteran participants must be willing to provide informed consent to participate in the study and consent to share treatment information with their GP as required.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
46

Key exclusion criteria
Veteran patients: For veteran patients who will receive R&R and TAU, 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 service branch.

We will exclude veteran participants:
1. Who are not aged 18 years or more
2. Who do not have military-attributable moral injury-related mental health problems as determined by their clinician
3. Have speech or hearing difficulties or serious cognitive impairment
4. Are actively self-harming or expressing significant suicidal ideation
5. Are unwilling or unable to provide informed consent
6. Have received trauma-focused individual therapy within last 3 months or have planned concurrent psychological therapy treatment
7. Who present with severe psychotic disorder (including in previous clinical diagnosis)
8. Who are experiencing dissociative identity disorder or other severe mental health difficulty
9. Who are currently experiencing significant life stressors that would impair the participant's ability to engage in therapy (e.g. homelessness)
10. Who have current alcohol or drug use disorder or dependency requiring further support or treatment that would significantly impact treatment engagement, as assessed by clinician
11. Who do not have internet access or are unwilling to complete sessions remotely
12. Who participated in the R&R pilot trial and previously received R&R (added 20/06/2023)

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

Date of first enrolment
06/07/2023

Date of final enrolment
01/07/2026

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
Combat Stress
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Sponsor information

Organisation
Forces in Mind Trust

ROR
https://ror.org/00jnzhe32

Funder(s)

Funder type
Charity

Funder Name
Forces in Mind Trust

Alternative Name(s)
FiM Trust, FiMT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study may be available upon reasonable request from Dr Williamson (victoria.williamson@kcl.ac.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/05/2024	21/05/2024	Yes	No