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Supporting health and social care workers with cognitive and behavioural coaching for posttraumatic stress disorder and depression

Submission date
20/02/2023

Recruitment status
No longer recruiting

Registration date
21/02/2023

Overall study status
Ongoing

Last Edited
28/04/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Frontline health and social care staff are routinely exposed to potentially traumatic events as part of their jobs. Coupled with occupational pressures, such as irregular shift patterns, and understaffing, the cumulative effects of such stress elevate the risk of developing post-traumatic stress disorder (PTSD) and major depression. In addition to experiencing work-related trauma, previous studies have discovered that many health and social care workers experience trauma outside of work, making them a vulnerable population to experiencing PTSD and other mental illnesses. It is therefore important that psychological therapies are readily and easily available for health and social care workers who suffer from such disorders to ensure that their mental health is taken care of and allow them to continue working.
SHAPE, originally funded by the University of Oxford COVID Research Response Fund, is a brief, accessible, remotely delivered intervention that targets cognitive processes and behaviours that maintain PTSD and depression, specifically rumination, unwanted memories, avoidance, and low mood. Pilot work demonstrated that SHAPE coaching achieved clinically significant change in PTSD and depression symptoms within 6 weeks compared to little change achieved during a 3-week monitoring phase. Of the healthcare workers who were diagnosed with PTSD in the study, 91.5% achieved reliable recovery with SHAPE and 71.4% achieved reliable recovery from major depressive disorder. However, due to the design of the pilot study, it is unclear whether the clinical improvements seen with SHAPE are associated with the intervention or with the passage of time.
This study aims to evaluate SHAPE using a gold standard method to establish whether or not the intervention leads to clinical improvements in PTSD and major depressive disorder, and is cost-effective.

The study aims to answer the following questions:
1. Does the intervention lead to recovery from PTSD and depression?
2. Is the reduction in symptoms during the intervention period greater than symptom change during an 8-week wait period?
3. Is the intervention effective, acceptable, and accessible to health and social care staff?
4. Does the intervention offer good value for money?

Who can participate?
Patient-facing health and social care workers (i.e., doctors, nurses, paramedics, care workers, occupational therapists, psychologists, physiotherapists, speech and language therapists, etc.) who are 18 years of age and older and have PTSD or major depression as their primary disorder.

What does the study involve?
Participants' symptoms of PTSD and depression are assessed using self-report measures and clinician-administered assessments. If a participant meets eligibility requirements, they are randomly allocated to receive the SHAPE intervention immediately or after 8 weeks (waitlist). The self-report and clinician-administered assessments are repeated at 8 weeks (post-intervention/waitlist), and 6 months to assess for symptoms of PTSD and depression. The SHAPE intervention involves completing approximately six coaching sessions over the course of 8 weeks (about one call per week) with a trained coach who specialises in PTSD and depression. Coaching sessions are conducted over the telephone and last about 40-60 minutes. In addition, participants are asked to complete brief weekly questionnaires that assess for changes in PTSD and depression. Participants are also assigned optional homework in the form of online computer modules after each session to consolidate learning.

What are the possible benefits and risks of participating?
All participants will have the option to access the SHAPE intervention during the trial. Participation could lead to recovery from PTSD and depression as well as improvements in participants' resilience and mental well-being.
Some of the questions in the questionnaires are sensitive and may trigger temporary feelings of distress. However, participants will have the support of their well-being coach, and the research team is also available to offer support if needed.

Where is this study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
October 2022 to October 2025

Who is funding the study?
1. NIHR Applied Research Collaboration Oxford and Thames Valley (UK)
2. Wellcome Trust (UK)
3. Oxford Health NIHR Biomedical Research Centre (UK)

Who is the main contact?
Miss Jasmine Laing, jasmine.laing@psy.ox.ac.uk

Study website
https://shaperecovery.com/

Contact information

Type(s)
Principal Investigator

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Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Supporting Hospital and Paramedic Employees (SHAPE) with cognitive and behavioural coaching for posttraumatic stress disorder and depression: a randomised controlled trial

Acronym
SHAPE

Study objectives
The SHAPE intervention will lead to fewer cases of post-traumatic stress disorder (PTSD) and major depression post-intervention compared to an 8-week wait period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/12/2022, Medical Sciences Interdivisional Research Ethics Committee (MS IDREC) (Research Services, Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB, UK; +44 (0)1865 616575; ethics@medsci.ox.ac.uk), ref: R80469/RE001

Study design
Single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Hospital, Internet/virtual, Telephone

Study type(s)
Treatment

Participant information sheet
https://oxfordxpsy.az1.qualtrics.com/jfe/form/SV_cC6RZ9DcWhwaILk

Health condition(s) or problem(s) studied
Post-traumatic stress disorder and major depression in patient-facing health and social care professionals

Interventions
Current interventions as of 05/04/2024:
Interested participants will be directed to the study's online information sheet and consent form. After reading the information sheet, if a participant is still interested in the trial, they will complete the following online consent form and be sent two screening questionnaires over email to assess for PTSD and depression (PTSD Checklist for DSM-5 [PCL-5] and Patient Health Questionnaire 9 [PHQ-9]). If the participant scores 20 or above on the PCL-5 for PTSD or 10 or above on the PHQ-9 for depression scale, they will be invited to take part in a telephone assessment. The telephone assessment will be conducted by an independent blinded assessor trained in administering the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) Structured Clinical Interview for DSM-5 (SCID-5). The assessor will conduct the SCID-5 assessment for both depression and PTSD with the participant. If a diagnosis* is made for either PTSD or depression the participant will be sent a second online consent form to take part in the trial. (*To ensure inter-rater reliability in SCID-5 diagnoses and prevent interviewer drift, the lead researchers will double-code a random selection of 20% of the telephone interviews over the course of the trial. In addition, the lead researchers will screen the first five interviews of each assessor for quality control.)

After receipt of the second consent form, an independent researcher separate from the core research team will randomly allocate the participant to either the intervention group or the waitlist group using a computer software program called Minim. This program randomly assigns participants using a minimisation method under our prognostic factors of MDD severity high/low on the PHQ-9 (median split 15), an absence or presence of PTSD using the DSM-5 SCID-5, and time since trauma (before or after 18 months).

Following randomisation, all participants will be sent a set of baseline questionnaires via email and receive a brief, standardised welcome call (10 minutes) with their assigned coach. Coaches will be trained mental health professionals/students who have completed the SHAPE training, had two successful training cases and attend weekly supervision sessions.

Participants assigned to the intervention group will begin SHAPE coaching with their assigned coach 1 week after completing their baseline questionnaires and welcome call. Participants will have approximately six SHAPE coaching sessions over the course of 8-weeks (approximately 1 session per week, factoring in holidays, time off work, and sick leave). Some participants may require an extra few sessions depending on the case complexity. Coaching sessions will take place over the telephone and last approximately 40-60 minutes. Participants will also complete a weekly set of online questionnaires, sent at the end of the week that they will need to complete before their weekly coaching session to track symptoms of PTSD and MDD and inform their coaching session. At four weeks (mid-intervention) participants will complete an extended set of online questionnaires to track for hypothesised mediators. At post-intervention (approximately 8 weeks), participants will complete a longer set of questionnaires and have another SCID-5 telephone assessment to assess for PTSD and depression. After 6 months, participants will receive a final set of questionnaires and have a final SCID-5 telephone assessment with an assessor who is blinded to the trial arm.

Participants assigned to the waitlist group will start the trial with a waiting period of 8 weeks with no contact from their assigned coach after their initial welcome call. Mid-way through the

waiting period (at 4 weeks) participants will receive the same set of extended questionnaires as the intervention group to track symptoms of PTSD and MDD, risk, and hypothesised mediators. At the end of the 8-week waiting period, participants will be sent the same longer set of online questionnaires as the intervention group and have a SCID-5 telephone assessment to re-assess for PTSD and depression. If a participant is still diagnosed with PTSD or depression and wishes to continue with the trial and have SHAPE coaching, they will begin the SHAPE intervention in 1-2 weeks at a time that suits them. Participants who choose to have the SHAPE intervention will follow the same process as the intervention group and be sent weekly online questionnaires, an extended 4-week set of online questionnaires, a longer set of post-intervention questionnaires, and a post-intervention SCID-5 telephone assessment. After 6 months participants in the waitlist group will be sent a final set of online questionnaires and have a SCID-5 telephone assessment.

After completing the intervention, a purposive sample of participants will also be invited to attend an online interview to collect PROM's information about the accessibility, acceptability, and overall satisfaction of the SHAPE intervention.

Previous interventions:
Interested participants will be directed to the study's online information sheet and consent form. After reading the information sheet, if a participant is still interested in the trial, they will complete the following online consent form and be sent two screening questionnaires over email to assess for PTSD and depression (PTSD Checklist for DSM-5 [PCL-5] and Patient Health Questionnaire 9 [PHQ-9]). If the participant scores 20 or above on the PCL-5 for PTSD or 10 or above on the PHQ-9 for depression scale, they will be invited to take part in a telephone assessment. The telephone assessment will be conducted by an independent blinded assessor trained in administering the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) Structured Clinical Interview for DSM-5 (SCID-5). The assessor will conduct the SCID-5 assessment for both depression and PTSD with the participant. If a diagnosis* is made for either PTSD or depression the participant will be sent a second online consent form to take part in the trial. (*To ensure inter-rater reliability in SCID-5 diagnoses and prevent interviewer drift, the lead researchers will double-code a random selection of 20% of the telephone interviews over the course of the trial. In addition, the lead researchers will screen the first five interviews of each assessor for quality control.)

After receipt of the second consent form, an independent researcher separate from the core research team will randomly allocate the participant to either the intervention group or the waitlist group using a computer software program called Minim. This program randomly assigns participants using a minimisation method under our prognostic factors of MDD severity high/low on the PHQ-9 (median split 15), an absence or presence of PTSD using the DSM-5 SCID-5, and time since trauma (before or after 18 months).

Following randomisation, all participants will be sent a set of baseline questionnaires via email and receive a brief, standardised welcome call (10 minutes) with their assigned coach. Coaches will be trained mental health professionals/students who have completed the SHAPE training, had two successful training cases and attend weekly supervision sessions.

Participants assigned to the intervention group will begin SHAPE coaching with their assigned coach 1 week after completing their baseline questionnaires and welcome call. Participants will have approximately six SHAPE coaching sessions over the course of 8-weeks (approximately 1 session per week, factoring in holidays, time off work, and sick leave). Some participants may require an extra few sessions depending on the case complexity. Coaching sessions will take place over the telephone and last approximately 20-40 minutes. Participants will also complete a weekly set of online questionnaires, sent at the beginning of the week that they will need to

complete before their weekly coaching session to track symptoms of PTSD and MDD and inform their coaching session. At four weeks (mid-intervention) participants will complete an extended set of online questionnaires to track for hypothesised mediators. At post-intervention (approximately 8 weeks), participants will complete a longer set of questionnaires and have another SCID-5 telephone assessment to assess for PTSD and depression. After 6 months, participants will receive a final set of questionnaires and have a final SCID-5 telephone assessment with an assessor who is blinded to trial-arm.

Participants assigned to the waitlist group will start the trial with a waiting period of 8 weeks with no contact from their assigned coach after their initial welcome call. Mid-way through the waiting period (at 4 weeks) participants will receive the same set of extended questionnaires as the intervention group to track symptoms of PTSD and MDD, risk, and hypothesised mediators. At the end of the 8-week waiting period, participants will be sent the same longer set of online questionnaires as the intervention group and have a SCID-5 telephone assessment to re-assess for PTSD and depression. If a participant is still diagnosed with PTSD or depression and wishes to continue with the trial and have SHAPE coaching, they will begin the SHAPE intervention in 1-2 weeks at a time that suits them. Participants who choose to have the SHAPE intervention will follow the same process as the intervention group and be sent weekly online questionnaires, an extended 4-week set of online questionnaires, a longer set of post-intervention questionnaires, and a post-intervention SCID-5 telephone assessment. After 6 months participants in the waitlist group will be sent a final set of online questionnaires and have a SCID-5 telephone assessment.

After completing the intervention, a random selection of participants will also be invited to attend an over-the-phone interview to collect PROM's information about the accessibility, acceptability, and overall satisfaction of the SHAPE intervention.

Intervention Type
Behavioural

Primary outcome measure
PTSD and major depressive disorder diagnoses measured using the DSM-5 SCID-5 clinician-administered assessment at 8 weeks post-intervention/post-waitlist

Secondary outcome measures
Current secondary outcome measures as of 20/07/2023:
1. PTSD and major depressive disorder diagnoses measured using the DSM-5 SCID-5 clinician-administered assessment at 6 months follow-up
2. Severity of PTSD, major depressive disorder, and generalised anxiety disorder symptoms, measured using the PTSD Checklist for DSM-5 (PCL-5), Patient Health Questionnaire (PHQ-9), and Generalised Anxiety Disorder Assessment (GAD-7) self-report scales respectively at baseline (pre-intervention/waitlist), 4 weeks (intervention/waitlist), 8 weeks (post-intervention/ waitlist), and at 6 months follow-up
3. Severity of complex PTSD and insomnia symptoms, measured using the International Trauma Questionnaire (ITQ), and the Insomnia Severity Index (ISI) self-report scales respectively at baseline (pre-intervention/waitlist), and 8 weeks (post-intervention/waitlist)
4. Rumination, responses to unwanted memories, and maladaptive appraisals, measured using the Response to Intrusions Questionnaire (RIQ-short), and the Post Traumatic Cognitions Inventory (PTCI-short) at baseline, 4 weeks (intervention/waitlist), 8 weeks (post-intervention /waitlist), and at 6 months follow-up
5. Resilience and well-being, measured using the Warwick Edinburgh Mental Wellbeing Scale (WEMWBS), the Connor Davidson Resilience Scale -25 (CD-RISC-25), and two social support

scales adapted from a brief measure of social support (Sarason et al., 1987) at baseline, 8 weeks (post-intervention/waitlist), and at 6 months follow-up
6. Health economics outcomes, measured using the iMTA Productivity Cost Questionnaire short (PCQ), Short Form Health and Labor Questionnaire (SF-HLQ), Client Service Receipt Inventory (CSRI) (edited), Recovering Quality of Life (Re-QoL) and the Quality of Life (EQ-5DL), collected at baseline, post-intervention/waitlist, and at 6 months follow-up
7. Qualitative outcomes of the SHAPE intervention, collected in the format of semi-structured interviews at post-intervention

Previous secondary outcome measures:
1. PTSD and major depressive disorder diagnoses measured using the DSM-5 SCID-5 clinician-administered assessment at 6 months follow-up
2. Severity of PTSD, major depressive disorder, and generalised anxiety disorder symptoms, measured using the PTSD Checklist for DSM-5 (PCL-5), Patient Health Questionnaire (PHQ-9), and Generalised Anxiety Disorder Assessment (GAD-7) self-report scales respectively at baseline (pre-intervention/wait-list), 4 weeks (intervention/waitlist), 8-weeks (post-intervention/ waitlist), and at 6 months follow-up
3. Rumination, responses to unwanted memories, and maladaptive appraisals, measured using the Response to Intrusions Questionnaire (RIQ-short), and the Post Traumatic Cognitions Inventory (PTCI-short) at baseline, 4 weeks (intervention/waitlist), 8 weeks (post-intervention /waitlist), and at 6 months follow-up
4. Resilience and well-being, measured using the Warwick Edinburgh Mental Wellbeing Scale (WEMWBS), the Connor Davidson Resilience Scale -25 (CD-RISC-25), and a social support scale adapted from a brief measure of social support (Sarason et al., 1987) at baseline, 8 weeks (post-intervention/waitlist), and at 6 months follow-up
5. Health economics outcomes, measured using the iMTA Productivity Cost Questionnaire short (PCQ), Short Form Health and Labor Questionnaire (SF-HLQ), Client Service Receipt Inventory (CSRI) (edited), Recovering Quality of Life (Re-QoL) and the Quality of Life (EQ-5DL), collected at baseline, post-intervention/waitlist, and at 6 months follow-up
6. Qualitative outcomes of the SHAPE intervention, collected in the format of semi-structured interviews at post-intervention

Overall study start date
01/10/2022

Completion date
31/10/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 05/04/2024:
1. Patient-facing health or social care worker – professions include: nurse, doctor, paramedic, care worker, ambulance service team member, midwife, allied health professional, mental health professional, healthcare support worker, medical associate, pharmacist, care assistant, or student training to deliver health or social care
2. Aged 18 years and older
3. Willing and able to provide informed consent
4. PTSD or major depression as their primary disorder
4.1. Score 20 or above on PCL-5 (PTSD)
4.2. Score 10 or above on PHQ-9 (Depression)

4.3. Diagnosed with PTSD or major depression on the SCID-5
5. Health and social care staff who are willing to be randomised
6. If taking psychotropic medication, the dose must be stable for at least 1 month before randomisation and remain stable throughout the trial
7. If currently receiving psychological therapy, this treatment must have ended before randomisation
8. Their current reexperiencing symptoms are linked to 1–3 discrete traumatic events

Previous inclusion criteria as of 20/07/2023:
1. Patient-facing health or social care worker – professions include: nurse, doctor, paramedic, ambulance service team member, midwife, allied health professional, mental health professional, healthcare support worker, medical associate, pharmacist, and nursing or medical student working in a hospital setting
2. Aged 18 years or older
3. Willing and able to provide informed consent
4. PTSD or major depression as their primary disorder
4.1. Score 20 or above on PCL-5 (PTSD)
4.2. Score 10 or above on PHQ-9 (Depression)
4.3. Diagnosed with PTSD or major depression on the SCID-5
5. Healthcare staff who are willing to be randomised
6. If taking psychotropic medication, the dose must be stable for at least 1 month before randomisation and remain stable throughout the trial
7. If currently receiving psychological therapy, this treatment must have ended before randomisation
8. Their current reexperiencing symptoms are linked to 1–3 discrete traumatic events

Original inclusion criteria:
1. Patient-facing health or social care worker – professions include: nurse, doctor, paramedic, ambulance service team member, midwife, allied health professional, mental health professional, healthcare support worker, medical associate, pharmacist, and nursing or medical student working in a hospital setting
2. Aged 18 years or older
3. PTSD or major depression as their primary disorder
3.1. Score 20 or above on PCL-5 (PTSD)
3.2. Score 10 or above on PHQ-9 (Depression)
3.3. Diagnosed with PTSD or major depression on the SCID-5
4. Healthcare staff who are willing to be randomised
6. Healthcare staff who are willing to remain on a stable dose of psychotropic medication for a mental health disorder if they are currently taking medication for it
7. Healthcare staff who are willing to not receive any other mental health treatment whilst in the RCT

Participant type(s)
Health professional, Learner/student

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
92 (46 per group). This number allows for 15% attrition.

Total final enrolment
92

Key exclusion criteria
Current exclusion criteria as of 05/04/2024:
1. Health and social care staff who do not have patient-facing roles e.g., administrators, lab technicians, receptionists, and maintenance workers.
2. Health and social care staff who do not meet DSM-5 criteria for PTSD and/or major depression
3. Health and social care staff who have a different primary disorder to PTSD or depression
4. Health and social care staff who present with imminent, persistent, clinically significant risk
5. Health and social care staff who request face-to-face treatment for PTSD or depression
6. Health and social care staff who would prefer a counselling approach or Improving Access to Psychological Therapies (IAPT)
7. Health and social care staff unwilling to be randomised or to stay on a stable dose of their current medication for a mental illness or to refrain from seeking other mental health support during the trial

Previous exclusion criteria:
1. Healthcare staff who do not have patient-facing roles e.g., administrators, lab technicians, receptionists, and maintenance workers.
2. Healthcare staff who do not meet DSM-5 criteria for PTSD and/or major depression
3. Healthcare staff who have a different primary disorder to PTSD or depression
4. Healthcare staff who present with imminent, persistent, clinically significant risk
5. Healthcare staff who request face-to-face treatment for PTSD or depression
6. Healthcare staff who would prefer a counselling approach or Improving Access to Psychological Therapies (IAPT)
7. Healthcare staff unwilling to be randomised or to stay on a stable dose of their current medication for a mental illness or to refrain from seeking other mental health support during the trial

Date of first enrolment
24/02/2023

Date of final enrolment
14/11/2024

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
University of Oxford
Centre for Anxiety Disorders and Trauma
Paradise Square
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Sponsor information

Organisation
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Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research Applied Research Collaboration Oxford and Thames Valley

Alternative Name(s)
NIHR ARC Oxford and Thames Valley, NIHR Applied Research Collaboration Oxford and Thames Valley, Oxford and Thames Valley NIHR Applied Research Collaboration, NIHR Oxford and Thames Valley Applied Research Collaborative, National Institute for Health and Care Research (NIHR) Oxford and Thames Valley Applied Research Collaboration, NIHR Applied Research. Collaboration (ARC) for Oxford and the Thames Valley, ARC OTV, OTV ARC, NIHR ARC OTV, NIHR ARC-OxTV, ARC OxTV

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Funder Name
Oxford Health NIHR Biomedical Research Centre

Results and Publications

Publication and dissemination plan
The results will be published in peer-reviewed scientific journals with open access.

Intention to publish date
31/10/2026

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the study will be stored in a publicly available repository with a link to this repository being made available in the near future.

Participants in this study have given permission for their aggregated anonymised data to be shared with a data repository, such as Ox-data or the UK data archive and other responsible researchers. For participants who consent to their raw research data to be given to other researchers, including those working outside of the UK and the EU, to be used in other research studies, this will be available upon request from Prof. Jennifer Wild (jennifer.wild@psy.ox.ac.uk). Raw data will be anonymised and participants will be unidentified. The raw data will become available after the publication of the results of the trial and process analyses so that they can be used for meta-analyses or specified additional analyses. Only numerical raw data from the self-report questionnaires and SCID-5 assessments will be made available to other researchers. Audio recordings from the SCID-5 assessments and the qualitative interviews with participants will not be made available and will be destroyed at the completion of the study.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol (preprint)		17/04/2025	28/04/2025	No	No
Statistical Analysis Plan		25/04/2025	28/04/2025	No	No