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A study on providing time at work to support the mental health and well-being of emergency ambulance paramedics

Submission date
03/11/2025

Recruitment status
Not yet recruiting

Registration date
06/11/2025

Overall study status
Ongoing

Last Edited
21/01/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Emergency Medical Service (EMS) workers, including paramedics, are more likely to experience mental ill health and die by suicide than the general population in connection with the unique demands of their job. While support is available, the offered support is not always used. Research found that stigma, workplace culture, worries about seeking help, and a lack of time, stopped some staff from talking about or seeking help for their mental health. By comparison, when time, training, and a culture where staff felt genuinely cared for by their employer are provided, staff say they are more likely to seek help when needed.
The EMS-SHIELD study aims to improve mental health support by testing a workplace intervention designed for ambulance employees. Four ambulance stations, located in urban and suburban areas, will take part. Two stations will be randomly selected to provide the intervention to volunteer paramedics, while the other two will continue their usual support practices. Trained ambulance workers will provide one-hour peer-to-peer supportive 'time-to-talk' sessions during work hours. Carefully designed with input from ambulance staff, patient representatives, experts, and previous research, volunteer staff will be given the option to attend, reschedule, or decline their session, and all workers will still have access to usual services. To see if this approach is useful for ambulance staff, the number of paramedics who choose to take part will be counted, along with how many finish the study. Their thoughts will be gathered through interviews, and the answers to questionnaires will be checked to see if there are any changes in how they feel or how likely they are to ask for help when they need it. This information will be used to decide whether a larger research study (a randomised controlled trial) of this approach would be useful for ambulance staff and possible to undertake in live ambulance settings.

Who can participate?
1. Aged 18 years or above
2. HCPC-registered paramedic (including bank staff and paramedics working light duties)
3. Based primarily (50% shifts or more) at a participating ambulance station
4. Willing and able to give informed consent for participating in the study

What does the study involve?
The study involves recruiting four ambulance staff who are trained in 'clinical supervision' who have the skills and confidence to provide the one-hour supportive session for each paramedic who volunteers to join in the study. Training will be provided to enable the delivery of a structured session that includes time for the paramedic to think about their job and how it makes them feel, information about the mental health support offered by their employer, and opportunity to help the paramedic to consider what works for supporting their own mental health by completing a wellness action plan.
Four ambulance stations have been earmarked to participate in this study. Two of the four stations will be randomly assigned to provide the intervention, where paramedics who agree to join in the study will be provided with protected time in work hours for a chat with a trained peer to think about their work and their own mental health and well-being needs. The other two stations will be randomly assigned to be 'usual practice' sites and paramedics from those stations will provide vital information about what they would usually do when support is needed at work. The information we collect about whether paramedics in the intervention sites are happy to attend sessions, whether the sessions can be delivered in the same way each time, and whether sessions are interrupted by 999 calls or not, will help us to understand if this approach is welcomed by paramedics and whether it is possible to provide dedicated time in different ambulance service settings. In addition, all paramedics who agree to take part in the study will be asked to fill in three questionnaires, at three different time points, to help us to understand whether they are happy to complete this type of information during a research study. Those who complete all three questionnaires will be offered a £30 thank you gift voucher. This will help us to understand whether the information we collect, such as well-being scales and attitudes towards help-seeking, is likely to be useful if we repeat this approach in a larger scale study across more ambulance stations and different ambulance service organisations in the future. Everyone who takes part, including people who deliver the sessions and ambulance managers who help the trial to take place in the designated ambulance stations, will be invited to take part in an interview after the sessions have been provided to talk about their experiences of being part of the study. People who join the interviews will each be offered a £40 gift voucher to thank them for their time.

What are the possible benefits and risks of participating?
Taking part in this study may help improve future support at work for ambulance staff well-being, whilst providing ambulance paramedics who join the trial with insight into their own mental health and space to think about how they can seek support if needed. The paramedics who take part will be offered thank you gift vouchers for completing questionnaires or interviews, and if their response suggest that they may be experiencing difficulties, such as symptoms of post traumatic stress disorder, they will be given guidance and provided with further support if required. Nonetheless, it may be upsetting for some people to think about work-related experiences and their mental health. Trained facilitators will provide a safe, confidential space and paramedics who go to their dedicated session can pause or stop at any time if they feel upset. In rare cases, sessions may be interrupted if the paramedic is urgently needed for an emergency call – if this happens arrangements will be made to reschedule their session for another time. Overall, while there are some emotional risks in taking part, support and safeguards have been put in place to minimise them.

Where is the study run from?
One NHS ambulance service in South West England (UK)

When is the study starting and how long is it expected to run for?
October 2022 to December 2026

Who is funding the study?
The National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Sasha Johnston, sasha.johnston@psy.ox.ac.uk

Contact information

Type(s)
Scientific

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Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
354334

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

CPMS 67412; Grant Code: NIHR302983

Study information

Scientific Title
Supporting Health, Improving Employee Life and Duty (SHIELD): a cluster randomised controlled feasibility trial of dedicated time at work for improving Emergency Medical Service worker mental health

Acronym
EMS-SHIELD

Study objectives
Primary objectives:
Feasibility and acceptability of the approach to EMS paramedics.

Secondary objectives:
1. Provide estimates of statistical quantities for the well-being, attitudinal, and symptom outcomes in each arm to inform sample size calculations for a larger definitive trial of the intervention versus treatment-as-usual (TAU).
2. Feasibility of collecting data for a full economic evaluation. Provide estimates of statistical quantities for the health economics outcomes in each arm, which will be used to inform a definitive trial of EM-SHIELD to TAU.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/10/2025, Bromley Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, London, E29 1JQ, UK; +44 (0)207 1048124; bromley.rec@hra.nhs.uk), ref: 25/LO/0682

Study design
Randomized; Interventional; Design type: Prevention, Process of Care, Education or Self-Management, Psychological & Behavioural, Complex Intervention

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Mental health

Interventions
This study will be a 6-month cluster randomised feasibility trial comparing usual practice (individuals contact organisational support services unprompted) to EMS-SHIELD. Preliminary findings suggest that this will entail a 1-hour, trained peer-to-peer, trauma-informed, time-to-talk session scheduled during working hours (tailored in accordance with study 2 and 3 findings).

During the session employees will reflect upon how they feel about work-related experiences, be updated about available support, and signposted to further support as needed.

Design:
Acceptability and feasibility testing of EMS-SHIELD will be conducted in two phases:
1. A cluster randomised feasibility trial in one geographically defined site within one UK ambulance service trust will compare usual practice (no dedicated time at work and individuals contact organisational support services unprompted) to the EMS-SHIELD intervention (dedicated, structured time at work).
2. Process evaluation.

Methods:
The unit of clustering at each site will be an ambulance station. The clusters will comprise paramedics based at eligible stations who volunteer to participate in the trial. Once participants are recruited and ambulance stations are randomly allocated to intervention or control groups, participating paramedics based at those stations will be asked to participate in organisational support for their mental health and well-being according to their group allocation: either a 1-hour EMS-SHIELD session (intervention group) or usual practice (no dedicated time at work, but access to organisational support services as required). Both groups will be asked to complete baseline and follow-up data collection questionnaires which are anticipated to take each participant approximately 30 minutes to complete at each timepoint. Funding is available for thank you gift vouchers to thank participants for their time in completing questionnaires.

Participants:
HCPC registered paramedics aged 18 years or over employed by South Western Ambulance Service NHS Foundation Trust (SWASFT) with their base station registered as one of the 4 ambulance stations chosen to participate in this trial. To inform our understanding of the feasibility, part-time as well as full-time paramedics will be included to enhance generalisability and to inform understanding about the adaptability of this approach to varying shift structures.

Recruitment and Consent
Two urban and two suburban EMS stations were chosen for this trial following consultation with ambulance service operational and research leaders, in areas representing diverse populations (in and around one of South West England's largest cities) with the resources to participate. The decision to include only four cluster units is based on practicality, methodological rigor, and ethical considerations. A smaller number of clusters allows for focused resource allocation, ensuring structured implementation and monitoring without overextending logistical capacity. The four chosen stations are:
1. Bristol ambulance station (urban)
2. Keynsham ambulance station (suburban)
3. Weston-Super-Mare ambulance station (urban)
4. Nailsea ambulance station (suburban)

Urban EMS stations are based in cities or large towns, whilst suburban stations are based in small towns or large villages outside of the urban setting. An information sheet with an overview of the research plan will be provided for the overseeing ambulance service County Commander. The County business administrators will arrange for emails to be sent to all paramedics registered at the earmarked stations on behalf of the CI, inviting them to read the PIS, ask questions and provide consent to participate if interested.

Intervention facilitators will be invited to participate via direct work emails drawn from a list of registered clinical supervision facilitators sent by the participating ambulance service on behalf

of the CI. The CI will also present the study at a facilitator group meeting. Volunteer facilitators will provide written consent to participate in the trial after reviewing the PIS specifically designed for facilitators. They will agree to undertake Good Clinical Practice (GCP) training and a short intervention training course with the CI to promote consistency across intervention delivery based on study 3's intervention manual. As part of this training process, they will also sign a confidentiality agreement, formally committing to uphold the confidentiality and data management requirements throughout the intervention. Funding has been secured via the Regional Research Delivery Network (South West England) for 4 facilitators to undertake this training in work hours.

Employee PIS', sent with invitations asking paramedics to participate, will be distributed via internal email by ambulance county business administrators on behalf of the CI. They will also support distribution of visual adverts, such as posters, which will be shared in the secure, security pass protected, participating ambulance service buildings and via internal social media and in-station TV. The CI will present the study at relevant EMS station meetings and a recruitment video co-produced with PPIE representatives and recorded by a patient and public representative will invite employees to participate. This decision was informed by preparatory PPIE work where employee and patient representatives believed recruitment would be maximised if links were drawn between employee and patient care (especially for employees who may be resistant or less interested in mental health initiatives or research).

If employees decide that they wish to participate, they will have the option of providing consent online or to ask further questions; researcher contact details will be provided (email and telephone). Once participants' questions have been answered or if they have no questions and wish to give their consent, they will be required to confirm that they understand the various points of the study after reading the PIS and electronically sign their name. Once they have given consent online, they will be asked to complete one screening questionnaire. It will be made clear that participation is entirely voluntary and that volunteers may withdraw from the study at any point without incurring any negative consequences.

Screening and Eligibility Assessment:
We will screen out any persons who are not registered to work from participating ambulance stations as an HCPC-registered paramedic, or have participated in preparatory studies as per the inclusion and exclusion criteria. Volunteer participants will be asked to complete a baseline questionnaire which consists of baseline characteristics: age range, gender, job role, base station, length of service, whether they have previously utilised organisational support for their mental health, whether they would use organisational support in the future, and contact details alongside their preferred method of contact. Any persons who do not meet the inclusion criteria will be sent a thank you email with confirmation of why they weren't eligible.

Randomisation:
To reduce selection-bias, paramedics will be recruited and then cluster randomisation will be employed, with the station as the cluster. A web-based random generator will allocate one urban and suburban site to the intervention and control groups. Limiting the geographical area is practical and avoids cross-contamination to other areas that may participate in the future RCT.

Over-Recruitment Contingency Plan:
If larger stations with higher numbers of paramedics are randomised to the intervention and the number of consenting paramedics exceeds n = 32 (the estimated number of intervention arm paramedics that have been costed for), random sampling will be employed by using a web-based random generator to select anonymised participant identifiers allocated to the pool of consenting paramedics. This method ensures that all consenting paramedics have equal chance

of being included – the potential for random sampling will be made clear in the participant PIS. Any consenting non-selected paramedics will be entered into a prize draw with a chance to win one £40 thank you gift voucher.

Intervention:
One-hour structured session in work hours for EMS employee mental health and well-being. Based on preparatory work so far, this is likely to include time to reflect on work with a trained peer, education about the support available through employee services, and completion of a wellness action plan.

Control Condition:
Standard practice (no dedicated time).

Intervention Group:
Paramedics at participating clusters are notified of their designated EMS-SHIELD timeslot and presented with the following options:
1. Attend their allocated session.
2. Request a different time slot.
3. Email the researcher to advise of non-attendance; A short voluntary online questionnaire will be returned to explore non-attendance reasons, alongside an email ascertaining willingness to complete questionnaires at 4-weeks post-randomisation, and 3-month follow-up.
All participants will still have access to usual practice.

Control Group:
Usual practice – individuals contact organisational support services unprompted and no dedicated time is provided at work. Paramedics allocated to continue 'usual practice' will complete questionnaires, including the utilisation of 'usual practice' for informing a future RCT at baseline (before randomisation), within 4 weeks post-randomisation, and at 3-months post-randomisation. Participants who complete questionnaires at each time point will be provided with one £30 thank you e-voucher (£10 per completed questionnaire) after the final 3-month post-randomisation questionnaire is completed.

Data Collection:
Data will be collected from participants and EMS-SHIELD session facilitators at baseline (pre-randomisation), 4 weeks post-randomisation, and 3-months post-randomisation.

Safety and Ethical Considerations:
Ensuring psychological safety is paramount. Discussions may cause distress, and participants can withdraw at any time. A Clinical Supervision framework will guide the intervention. Psychological support services offered by the participating NHS Ambulance EMS Trust will be available. Adverse incidents will be reported and reviewed according to protocol. PCL-5 scores ≥30 will trigger guidance messages and follow-up emails for support.

Data Analysis:
Sample size: 128 paramedics across four stations; aim to recruit 64 (32 per group). Feasibility parameters will be measured with sufficient precision. Descriptive statistics and confidence intervals will be reported. No formal hypothesis testing; treatment effects will inform future trial design.

Process Evaluation
Qualitative interviews (n = 16):
6 intervention participants

6 control participants
2 facilitators
2 station managers

Interviews will explore acceptability, adherence, and contextual factors. Data will be analysed using reflexive thematic analysis framed by COM-B and TDF.

Intervention Type
Other

Primary outcome(s)
The feasibility of the approach to inform the design of a future definitive trial:
1. Feasibility outcomes (measured at baseline, within 4-6 weeks, and 3-months post-randomisation):
1.1. Recruitment rate (percentage of eligible paramedics recruited)
1.2. Retention rate (percentage retained at follow-up points)
1.3. Data collection feasibility (completion rates for questionnaire measures)
1.4. Time needed to collect and analyse data
1.5. Adherence to the EMS-SHIELD intervention by facilitators (fidelity checklists to completed by the facilitators - including any reasons for session interruption, e.g., major incident)
2. Acceptability outcomes (measured at baseline, within 4-6 weeks, and 3-months post-randomisation and via process evaluation interviews for select participants):
2.1. Attendance rates (session participation)
2.2. Session ratings (intervention satisfaction)
2.3. Intervention experience
2.4. Self-report Theoretical Framework of Acceptability (TFA) questionnaire (all participants)
2.5. Process evaluation qualitative interviews (subset of participants)

Key secondary outcome(s))
Measured at baseline within 4-6 weeks, and 3 months post-randomisation:
The secondary objectives of this study aim to inform sample size calculations and estimate statistical quantities for health economic outcomes for a larger definitive trial of the intervention versus treatment-as-usual (TAU) by collecting the following data:

1. Participant-focussed questionnaires:
1.1. Attitude towards help-seeking short form
1.2. Perceived Organisational Support
1.3. PTSD checklist (PCL-5)
1.4. Trauma exposure checklist (LEC-5)
1.5. World Health Organization-Five Well-Being Index (WHO-5)

2. Health economic questionnaires:
2.1. Health-related Quality-of-Life (HRQoL) EQ-5D-5
2.2. Mental health specific Recovering Quality of Life (ReQoL-10)
2.3. Intervention e.g., frontline backfill, preparation and post session time
2.4. Other resource use/costs e.g., using a modified (with PPI/E support) Client Service Receipt Inventory form at the 3-month post-randomisation time point, to capture participants' use of health and social care (e.g., GP visits; medications), travel time to/from health treatments/visits, as well as any time off work, and all associated costs.

We will also evaluate whether the following progression criteria have been met, prior to planning a future definitive trial:

Intervention:
1. Feasibility measure: sign up four EMS stations, including ≥50% recruited by eligible staff at each site.
2. Acceptability measure: ≥60% of consenting paramedics attend allotted IMPACT sessions

Trial methods:
1. Feasibility measures: ≥75% of participants complete data collection and changes in participant well-being will yield trends in the predicted direction (improves).
2. Acceptability measures: qualitative process evaluation findings include intent to continue use of EMS-SHIELD approach and perceived appropriateness for organisational practice.

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study.
2. Aged 18 years or above.
3. HCPC registered paramedic employed by South Western Ambulance Service NHS Foundation Trust (SWASFT) with their base station registered as one of the four ambulance stations chosen to participate in this trial.
4. Based primarily (50% shifts or more) at participating ambulance station.

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Non-paramedic (including student paramedic)
2. Prior participation in preparatory focus groups

Date of first enrolment
01/04/2026

Date of final enrolment

01/06/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bristol ambulance station (urban)
Croydon Street
Easton
Bristol
England
BS5 0DA

Study participating centre
Keynsham ambulance station (suburban)
4 West View Road
Keynsham
Bristol
England
BS31 1BS

Study participating centre
Weston-Super-Mare ambulance station (urban)
61 Drove Road
Weston-Super-Mare
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BS23 3NT

Study participating centre
Nailsea ambulance station (suburban)
47 Clevedon Road
Nailsea
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BS48 1HA

Sponsor information

Organisation
South Western Ambulance Service NHS Foundation Trust

ROR
https://ror.org/009dhvf97

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository within the University of Oxford by the end of 2026. Anonymised data may be accessed and analysed by authorised representatives from the University of Oxford supervision team and representatives from the Sponsor's research and development team (host institution - SWASFT) for monitoring and/or audit of the study to ensure compliance with regulations. With the exception of anonymised quotes from research interviews and participant feedback, consent from participants was not sought for sharing raw data publicly.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	version 2.0	29/09/2025	06/11/2025	No	Yes
Participant information sheet	version 2.0	29/09/2025	06/11/2025	No	Yes
Participant information sheet	version 2.0	29/09/2025	06/11/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes