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Providing dedicated time in work hours for paramedic well-being: A feasibility study

PARTICIPANT INFORMATION SHEET - Facilitators

Ethics Approval Reference: IRAS ID 354334

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Study title - EMS-SHIELD

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 [NIHR 302983].

Researcher Introduction

My name is Sasha Johnston, and I am a DPhil student at the University of Oxford and SWASFT Research Paramedic. I would like to invite you to take part in a research study that has been funded by the National Institute for Health and Care Research (NIHR) that I am completing as part of my Doctorate qualification.

Introduction

Before you decide whether to take part or not, it is important for you to understand why the research is being conducted and what it will involve. Please take the time to read this participant information sheet carefully.

The study is part of a DPhil research project aimed at exploring the feasibility and acceptability of providing time for employee well-being and reflection in work hours. The data collection may contribute to publications, presentations, and a DPhil thesis. At no time will any personally identifiable data be published. In this research study we will use information from you. We will only use information that we need for the research study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study we will save some of the data in case we need to check it and for future research. We will make sure no-one can work out who you are from the reports we write. The following information pack tells you more about this.

Background and purpose of the research

Emergency ambulance work carries risk of stress and mental ill health. While support services exist, many staff don't seek help. Our research found that ambulance employees want dedicated time during work hours that aligns with their professional identity, to enable them to reflect on work-related experiences, their well-being, and access tailored support if needed. We know that well-supported staff provide better patient care.

This study, shaped by ambulance employees' experiences and patient perspectives, will test whether providing dedicated, structured time during work hours is feasible and acceptable for paramedics. Findings will inform the development of future research to assess the impact of this approach on employee mental health and well-being.

Why have I been invited to take part?

You have been invited to take part in this study as you are a **HCPC-registered paramedic** and **qualified clinical supervision facilitator** registered with SWASFT's clinical supervision facilitator team, who is over the age of 18 years and able to provide structured, timed sessions from **Bristol, Keynsham, Nailsea, or Weston-Super-Mare ambulance stations** during this study. You are invited to facilitate the EMS-SHIELD sessions because of your training, skills, and knowledge of delivering Clinical Supervision. We will recruit 4 intervention facilitators for this trial.

The **exclusion criteria** are paramedics not registered as clinical supervision facilitators with SWASFT, and those unable to facilitate sessions from the participating ambulance stations. Paramedics, the most likely staff group to be exposed to work-related traumatic experiences, are the focus of this feasibility trial, but future research aims to include all roles, recognising that anyone in ambulance services can be affected by their work.

Do I have to take part?

No. Participation in this study is entirely voluntary. If you choose not to participate, this will not affect your professional role or future opportunities. You can also withdraw from the study at any time without giving a reason. If any of the 4 facilitator's withdraw we may recruit a replacement. Whether we recruit and how quickly we do so will depend on the availability of the remaining facilitators and how far the trial has progressed. Any

replacement will receive the same training and oversight, and we will manage handover so that participants experience as little disruption as possible. If necessary, existing facilitators may provide temporary cover. This could affect scheduling, workload, and supervision; we will keep the facilitator team informed and offer support.

What would taking part involve?

Four ambulance stations have been earmarked to participate in this trial and paramedics working in those stations will be invited to sign up to be part of this research. Two of the four stations will then be randomly assigned to be intervention sites where consenting paramedics from those stations are provided with protected time in work hours for a chat with a trained peer (you) to reflect on work and think about their own needs. The other two stations will be randomly assigned to be 'usual practice' sites and paramedics from those stations will provide vital information about 'usual practice' as detailed in the table on page 4. If you are happy to take part in the study as an intervention facilitator, **you will be asked to confirm that you have read this participant information sheet and to complete and sign a consent form.**

To test the feasibility and acceptability of providing time for employee wellbeing in work hours we have identified four ambulance stations, two in urban areas (Bristol and Weston-Super-Mare) and two in suburban areas (Nailsea and Keynsham). This gives us information about whether it is easier or harder to deliver this type of intervention in different settings, whilst keeping the study area small so we don't unduly create barriers to where we can hold a larger scale trial in the future. We will invite all the paramedics from these stations to participate.

Your role in the trial will be to facilitate up to 8, one-hour clinical supervision sessions that will be planned in advance based upon participant working hours, convenience, and your availability. As a facilitator, you cannot also participate in the study as a participant. We will ask you to deliver approximately 2-4 sessions per day from one of the participating ambulance stations. You will provide paramedics with space and time to reflect on work-related experiences, complete wellness action plans, be updated about current staying well service support options, and be signposted to support services if needed. We will aim to recruit four facilitators to deliver the sessions for this trial. Backfill costs have been funded, and **you will be able to deliver these sessions in work hours.** If you agree to take on the role of a trial intervention facilitator, we ask that all facilitators follow a consistent approach in delivering sessions. To achieve this, each facilitator will be expected to undertake the following:

Complete NIHR Good Clinical Practice training

You will be asked to complete the NIHR Good Clinical Practice (GCP) Introduction e-learning course. This course provides essential knowledge on ethical research conduct and regulatory compliance for clinical trials and takes up to 4 hours to complete. Funding is available for this to be completed within work hours.

Attend a training session

This will entail a 4-hour training session which aims to refresh and consolidate your knowledge and build confidence in delivering clinical supervision sessions, train you on wellness action planning, and update you on current employee assistance support options. You will receive a tailored training package, with plenty of time for questions and answers with lead researcher Sasha Johnston at a venue to be agreed (likely the North Education Centre at UWE). Again, funding is available for this to occur within work hours.

Confidentiality agreement

During the training session you will be asked to read, ask any questions, and sign a confidentiality agreement that outlines your obligations in relation to confidentiality and protecting the data of participants in this trial.

Data collection

Once you are trained we will ask you to deliver the EMS-SHIELD intervention and to complete a fidelity checklist, which provide information about whether sessions were delivered consistently, whether there were any challenges or interruptions, alongside any thoughts you would like to share about session delivery.

Trial design

To make the study design as fair as possible, a technique called cluster randomisation will be used. This means that we recruit paramedics from participating ambulance stations by sending them an invitation email and participant information sheet. We will then use an online picker to randomly allocate one urban ambulance station and one suburban ambulance station to be 'usual practice' sites (option 1) and one urban ambulance station and one suburban ambulance station as intervention sites' (option 2) as per the following table:

Station is Randomly allocated to:	What will happen?	How many forms will I need to fill in?	How long will this take, and when will this be done?
Option 1: Practice as usual	Every consenting paramedic in these two stations will continue usual working practice and self-refer to support services if needed. Paramedics allocated to this group will provide valuable information about what 'practice as usual' looks like to help us design a future trial via a set of three questionnaires. You won't be involved with this aspect of the trial.	None	None

Option 2: Intervention	Every consenting paramedic in these two stations will be offered a one-hour dedicated, structured session time in working hours. They will be given the option to choose an alternative time if the first time offered slot is not convenient. The EMS-SHIELD session will involve a one-to-one chat with a trained peer (you), using a clinical supervision framework, in a quiet place on station.	One fidelity checklist for each EMS-SHIELD session delivered	You agree a schedule and will be given 90 minutes in work hours to deliver each EMS-SHIELD intervention – 60 minutes for a 1:1 chat and 30 minutes to prepare and to complete your checklist.
Process evaluation			
Everyone (including facilitators) will be offered the opportunity to express their interest in attending an interview after the trial finishes to discuss their experiences and perceptions. This will be online, unless in-person, or telephone is preferred (a separate participant information sheet will be sent to you after the trial to provide details about joining in these interviews)		One expression of interest questionnaire	Approximately 45-60 minute interview in your own time. A £40 thank you voucher is provided

The decision about which option each station will be allocated to will be made by chance.

Deliver the Intervention

You will be asked to provide your availability to the lead researcher to enable the scheduling of sessions for paramedics who have consented to participate in the trial. You will arrive on station in time to set up your room and deliver the intervention as agreed during your training session. Up to 90-minutes per EMS-SHIELD session has been costed. The intervention will follow the usual confidential framework as outlined in SWASFT's clinical supervision policy.

Any consenting paramedics working from an ambulance station that is allocated to the intervention group option 2, will not be obliged to attend their scheduled EMS-SHIELD session, they are free to choose. If they do not wish to attend, this will not affect their professional role or future opportunities. If a paramedic does not attend their planned session, you will record this and notify the lead researcher who will send the individual a follow-up questionnaire. This will ask them whether they would be happy to share their reasons about why they didn't attend (as this is important information to build our understanding about the feasibility and acceptability of this approach), a box stating 'no comment' will be available if they don't want to share their reasoning. We will also ask the participant to confirm whether they are happy to continue in the trial by completing follow-up data collection questionnaires or whether they have changed their mind and would like to withdraw from the study.

Complete fidelity checklists

For each session you deliver you will be asked to complete a checklist. These checklists will be compared across all the sessions provided during the trial by the lead researcher, to identify any areas of variation or areas that need to be refined alongside any pertinent information such as; interruptions, no-shows, and the number of onward referrals to support services. You will also be asked to record your reflection about delivering the session, including what went well and what could have been done differently. All records will be anonymised, and participants will be identified by their study code only and not their name in any written documentation.

Participate in clinical supervision

You will be expected to participate in clinical supervision yourself, either with the lead researcher or a trained clinical supervision facilitator from SWASFT. It is important that you look after yourself during this trial and access to employee support services will be available throughout. Participating in clinical supervision will enable you to share your feelings and experience about delivering the intervention in confidence. Funding is in place for you to participate in clinical supervision in work hours (up to six 1-hour sessions during the trial period are costed for, which can be adjusted based upon your individual needs).

What are the possible benefits of taking part?

You will be helping to shape future research to examine better approaches for ambulance employee well-being, potentially benefiting the workforce as a whole. The study has been awarded funding which includes paying for backfill to enable you to undertake training, complete trial questionnaires and checklists, and deliver the intervention to paramedics during work hours. You will also be invited to express your interest in participating in a follow-up qualitative process evaluation interview to talk about your experiences and opinions about the trial design and the EMS-SHIELD dedicated time-at-work approach tested in this trial. Everyone who participates in an interview will be offered a £40 thank you gift voucher.

What are the possible disadvantages and risks of taking part?

While we do not anticipate any significant disadvantages or risks in taking part, supporting others to reflect upon employee support at work, work-related experiences, or mental health may cause emotional distress. You are trained to deliver a restorative clinical supervision framework, incorporating trauma-informed practice and ground rules such as confidentiality and safeguarding provisions, and will know how to guide and support participants. Aligned with the Trust Clinical Supervision policy, if the participant discloses any information that indicates that harm may be caused to them or others, you will work with the participant to seek help and report the risk through routine networks, such as the staying well service. Any such incidents will also be reported to the study team. If you or your participant experiences emotional distress during a session, you can pause for a short break. You will be able to discuss your concerns in your own clinical supervision. If concerns

persist for the participant after the break, you may offer them support, which could include signposting to the wellbeing services, to their GP, or other support avenue best indicated in the circumstances. Throughout the trial, you and the participants will have access to employee assistance psychological support provided by SWASFT.

To ensure minimal disruption to emergency response and maintain psychological safety during sessions, funding has been secured to backfill resources while staff attend their scheduled sessions. This approach will be carefully monitored to assess feasibility. All paramedics will have equal opportunity to attend sessions without interruption. However, as recommended by staff representatives involved in the study design, exceptions may occur if you or the participant are the nearest available resource to a subset of time critical, high-risk emergencies, such a cardiac arrest, myocardial infarction, stroke, or a major incident occurs, whereas the session will stop. In such cases, you as the EMS-SHIELD facilitator will record this occurrence and notify the lead researcher, who will arrange for the participant to be offered an alternative session date and time where possible.

What if something goes wrong?

It is very unlikely that you would be harmed by taking part in this type of research study. However, if you wish to complain or you have any concerns about this research please contact Sasha at sasha.johnston@psy.ox.ac.uk or Professor Wild at jennifer.wild@psy.ox.ac.uk or the study sponsor; Head of Research and Audit, Dr Sarah Black at sarah.black@swast.nhs.uk.

How will we use information about you?

We will need to use information from you for this research project. This information will include:

- Age range, gender, job role, base station, length of service, and contact details alongside your preferred method of contact.

This information will be used to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. SWASFT is the host organisation and sponsor of this research and is responsible for looking after your information. We will share anonymised information related to this research project with the following types of organisations:

- University of Oxford [Academic institution]
- The National Institute for Health and Social Care Research [Funder]
- Health Research Authority
- Association of Ambulance Chief Executives
- College of Paramedics
- NHS England

- Peer-reviewed journals

We will keep all information about you safe and secure by:

- Collecting the minimum amount of data possible to conduct the research.
- Storing any identifiable information from your initial screening questionnaire separately from trial data (such as fidelity trial checklists).
- Labelling your checklists with a code number.
- Keeping survey data anonymous (not collecting any identifiable information about you in relation to this aspect of the study).
- Storing and sharing any data via University of Oxford password protected, restricted access, secure OneDrive files and folders sharing mechanisms.

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. Your data will not be shared outside the UK and we will keep your study data for a maximum of 10 years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- You have the right to ask us to remove, change, delete, or request a copy of the data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this. We will verify your identity before releasing any data.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team.
- by sending an email via the e-mail addresses listed on this participant information sheet.
- by ringing us on 07825 826250 (Sasha Johnston's contact number).
- by contacting SWASFT's Data Protection Officer via email on Information.Governance@swast.nhs.uk.

If you have any further queries please contact sasha.johnston@psy.ox.ac.uk, or if you would like to raise an issue with the Sponsor of this study, please email sarah.black@swast.nhs.uk.

What else will happen to the data I provide?

Your **anonymised** research data may be accessed by authorised individuals from the Sponsor and regulatory authorities for monitoring and audit purposes. We will take steps to ensure individuals cannot be identified.

Will my participation be kept confidential?

Yes, all information collected as part of this research project will be kept **strictly confidential**. And no personally identifiable data will be included in any research findings or publications.

Who is organising and funding the research study?

This research is funded through Sasha Johnston's Doctoral Research Fellowship with the National Institute for Health and Care Research [NIHR 302983] and the South West England Regional Research Delivery Network. The University of Oxford and the NIHR research design service (RDS South West) have supported the development of this research. The University of Oxford provide supervisory and statistical support.

How have patients and the public been involved in this study?

A small, dedicated team of patient and public representatives support this study by reviewing documents and sharing perspectives about the influence of paramedic well-being and attitude on patient care and experience. A reference group of 20 ambulance employees have also supported the development of this research to ensure that lived experience has shaped the chosen approach and study design. SWASFT's Patient Involvement in Research Group have been involved since the beginning, reviewing plans, providing feedback, and ensuring that patient and employee experience and perceptions remain at the heart of this work.

Who has reviewed the research study?

This study has been reviewed and given favourable opinion by the NIHR funding selection committee, the Health Research Authority via the Integrated Research Application System (IRAS) and the South Western Ambulance NHS Foundation Trust Research and Development group. This means that the research meets ethical standards for participant safety, data protection, and scientific integrity.

What will happen to the results of the research study?

The results of this research project will be used to contribute to a greater understanding of the feasibility and acceptability of providing time at work for ambulance employee well-being, and may be published in academic journals, presented at conferences, or used in other academic outputs such as reports or presentations. This information will help us to decide whether this approach should be tested more widely and what are the best methods to do this. Additionally, the findings will be included in the researcher's thesis, which is part of the requirements for a DPhil. You can opt to receive a plain-language summary of the trial results by ticking the relevant box on the consent form or by emailing the study team with your name and preferred email contact address; we will send the lay summary to those who

opt in once the feasibility study findings are available. If you would like a copy of the final research results, please let us know, and we will be happy to share them with you when they are available.

Further information and contact details

If you have any questions or would like more information about this research **please contact:** Sasha Johnston, Department of Experimental Psychology, University of Oxford, email: sasha.johnston@psy.ox.ac.uk. If you have any concerns about the way in which the research has been conducted, please contact: Dr Sarah Black , Head of Research and Audit, SWASFT, email: Sarah.Black@swast.nhs.uk

Thank you for taking the time to read this information and for considering being part of this research.