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

PARTICIPANT INFORMATION SHEET

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 a higher 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, aligned with their professional identity, to reflect on work-related experiences and their well-being. This will prompt access to early intervention tailored support, rather than waiting for a crisis point to be reached. 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 an HCPC-registered paramedic** (including bank paramedics and those on light duties), over the age of 18 years, and your base station (or where you work at least 50% of your shifts) is **Bristol, Keynsham, Nailsea, or Weston-Super-Mare**, which are the four stations earmarked for this study.

The **exclusion criteria** are non-paramedics and students and any paramedic who participated in either the preparatory focus group qualitative study or eDelphi expert consensus study. 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.

What would taking part involve?

Four ambulance stations have been earmarked to participate in this trial and all 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 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, **you will be asked to confirm that you have read this participant information sheet and to complete and sign a consent form**. You will then complete a short confidential questionnaire asking for basic demographic information, confirmation of your base station, any dates when you would not be able to participate in the intervention, and what your preferred method of contact during the study will be. The screening questionnaires will be destroyed after use.

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. If you consent, you will be invited to complete a longer confidential trial questionnaire that measures wellbeing, trauma exposure, stress, perceptions of organisational support, and attitudes towards help-seeking, at three separate time points as described in the table below. This will help us to understand whether paramedics are happy to complete this type of data collection, and whether the data is likely to be useful if we repeat this approach in a larger scale trial.

The first questionnaire will be completed at 'baseline.' To make the study design as fair as possible, a technique called cluster randomisation will be used. This means that we will 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 questionnaires will I need to fill in?**	**When will I do this?**
Option 1: Practice as usual	Every consenting paramedic in these stations will continue usual working practice and self-	1. Baseline 2. 4-weeks and	In your own time – approximately 30

	refer to support services if needed. If you are allocated to this group you will provide valuable information about what 'practice as usual' looks like to help us design a future trial.	3. 3-months after random allocation	minutes for each questionnaire. One **£30 thank you gift voucher** will be provided for completing questionnaires at all three timepoints.
Option 2: Intervention	Every consenting paramedic in these stations will be offered a **one-hour dedicated, structured session time in work hours**, aligned with your scheduled working pattern and screening questionnaire preferences. You will be given the option to choose an alternative time if the first time offered slot is not convenient for you. The session will involve a one-to-one chat with a trained peer in a quiet place on station. The session format will follow guidelines outlined in SWASFT's Clinical Supervision policy.	1. Baseline 2. 4-weeks and 3. 3-months after random allocation	In your own time – approximately 30 minutes for each questionnaire. One **£30 thank you gift voucher** will be provided for completing questionnaires at all three timepoints. Intervention: 60 minutes in work hours to attend allocated session (planned within the 4 weeks following random allocation)
Process evaluation			
After the trial finishes, everyone involved will be offered the opportunity to express their interest in attending an interview 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	In own time. One **£40 thank you voucher** is provided

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

If your station is allocated to the intervention group option 2, you are not obliged to attend your scheduled EMS-SHIELD session, you are free to choose if you do not wish to attend and this will not affect your professional role or future opportunities. If you do not attend your scheduled session, or we are unable to agree a convenient time for your session, the lead researcher will send a follow-up questionnaire via your preferred method of contact. This will ask whether you would be happy to share your reasons about why you 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 you don't want to share your reasoning. We will also ask you to confirm whether you are happy to continue in the trial by completing follow-up data collection questionnaires or whether you have changed your mind and would like to withdraw from the study.

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 money for backfill to enable intervention participants to join a session at work and thank you gift vouchers for all participants who complete questionnaires at the three timepoints. You will also be invited to express interest in participating in a follow-up interview to talk about your experiences and opinions about the approach tested in this trial. Everyone who participates in an interview will be offered a £40 thank you gift voucher.

Another potential benefit of taking part in this study is the opportunity to receive valuable insights into your well-being. Following your initial baseline questionnaire, if your Post-traumatic Stress Disorder Checklist (PCL-5) scores indicate possible symptoms of PTSD, you will receive an end-of-survey message with guidance on next steps. Four weeks after your ambulance station has been assigned to either the intervention or usual practice, you will complete your next questionnaire. If your scores are high, you will receive an end-of-questionnaire message with advice, and a message will be sent to your preferred contact choice with support suggestions. We won't scrutinise your questionnaire responses for mandatory help-seeking, but if your scores are elevated at the final data collection phase, the lead researcher will personally reach out to explore any further support you may need.

What are the possible disadvantages and risks of taking part?

While we do not anticipate any significant disadvantages or risks in taking part, reflecting on employee support, work-related experiences, or mental health may cause emotional distress. Facilitators are trained in a restorative clinical supervision framework, incorporating trauma-informed practice, confidentiality, and safeguarding provisions to ensure a supportive environment. If any information is disclosed that indicates that harm may be caused to yourself or others, the facilitator will work with you to seek help and report the risk through routine networks, such as the staying well service. If emotional distress arises during your session, you may take a short break. If concerns persist after the break, you may be offered further support, which could include the provision of resources, signposting to the wellbeing service, to your GP or other support avenue best indicated in the circumstances. Throughout the trial, all 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 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. In such cases, the session will be paused, the facilitator will record the occurrence, and where possible, an alternative session date and time will be offered.

We have secured funding for up to 32 paramedics to be provided with the EMS-SHIELD session in the intervention sites and for 32 paramedics to complete 'practice as usual' questionnaires. However, if more than 64 paramedics sign up for the trial, we may not be able to include everyone who would like to take part and some applicants may not be selected. If this happens, a method called random sampling will be used to randomly select participants from an anonymised pool of consenting paramedics. Paramedics who register to participate but are not randomly selected in this instance, will be notified by email and entered into a prize draw, from which one individual will be randomly chosen to receive a £40 gift voucher.

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 your involvement 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, whether you have previously utilised organisational support for your mental health, whether you would use organisational support in the future, 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 trial questionnaire responses).
- Labelling your questionnaires with a code number.
- Keeping survey data anonymous (not collecting any identifiable information about you in relation to this aspect of the study).
- Exporting questionnaire responses from Qualtrics as Microsoft-excel files via a secure virtual private network restricted access folder on the University of Oxford network.
- Storing and sharing any data via University of Oxford 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 or delete 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.

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.

- 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. Your research data will be collected using the online Qualtrics surveys platform. Information will be downloaded from the platform and saved to servers owned and maintained by the University of Oxford as soon as practically possible and within 3 months, after which the data will be deleted from the platform.

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 organised and funded through Sasha Johnston's Doctoral Research Fellowship with the National Institute for Health and Care Research [NIHR 302983] and the South West 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.

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.