Co-producing an **A**mbulance **T**rust **N**ational fatigue risk management system for improved Staff **A**nd **P**atient **S**afety **(CATNAPS)**

This protocol has regard for the HRA guidance and order of content

FULL STUDY TITLE: Fighting fatigue in the NHS ambulance workforce: development, acceptability and feasibility testing of a comprehensive fatigue risk management system to improve staff and patient safety

SHORT STUDY TITLE / ACRONYM: **C**o-producing an **A**mbulance **T**rust **N**ational fatigue risk management system for improved Staff **A**nd **P**atient **S**afety **(CATNAPS)**

VERSION

Protocol Version	Summary of changes	Protocol Date
V1.1 DRAFT	NIHR approved version in contracting [NIHR Detailed Research Plan]	1 October 2021
V1.2	HRA format 308115 (approved 07 July 2022), 316598 (pending) UEA REC Ethical Approval 27.05.2022	20 June 2022

RESEARCH REFERENCE NUMBERS: NIHR HSDR 131776*

IRAS ID: 308115 (Work Packages 1 and 2) / 316598 (Work Packages 3 and 4)

STUDY REGISTRY NUMBER: researchregistry8078 (08 July 2022)

PROTOCOL VERSION NUMBER AND DATE: Version 1.2, 20 June 2022

** This study is funded by the National Institute for Health Research (NIHR) HSDR Programme [Project ref: NIHR131776]. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.*

University of East Anglia

CATNAPS Fighting Fatigue in Ambulance Services

NHS Health Research Authority

Key Study Contacts

Chief Investigator	Professor Kristy Sanderson School of Health Sciences, University of East Anglia NIHR ARC East of England Kristy.sanderson@uea.ac.uk
Study Manager	Dr Lucy Clark (until 12.06.2022) Dr Chiara Lombardo (from 13.06.2022) School of Health Sciences, University of East Anglia NIHR ARC East of England Lucy.v.clark@uea.ac.uk
Sponsor	Contracts Manager Research and Innovation Services University of East Anglia rin.reception@uea.ac.uk
Lead Organisation	Head of Research Management, Finance and PPI NHS Norfolk and Waveney ICB nwccg.RandDoffice@nhs.net
Funder(s)	National Institute of Health Research
Protocol contributors	Professor Kristy Sanderson, University of East Anglia
	Professor Julia Williams, University of Hertfordshire
	Dr Colleen Butler, Health & Safety Executive
	Dr Lucy Clark, University of East Anglia
	Associate Professor Sandra James, UEA/Office for Health Improvement & Disparities, EoE
	Mr Jeremy Dearling, PPI
	Mr Jonathan Rogers, Staff lived experience (PPI)/UEA
	Dr Bryony Porter, University of East Anglia
	Dr Chiara Lombardo, University of East Anglia

LIST of CONTENTS

GENERAL INFORMATION	**Page No.**
HRA PROTOCOL COMPLIANCE DECLARATION	1
TITLE PAGE	1
RESEARCH REFERENCE NUMBERS	1
LIST OF CONTENTS	2
KEY STUDY CONTACTS	3
STUDY SUMMARY	4
FUNDING AND SUPPORT IN KIND	5
LIST OF ABBREVIATIONS	5
ROLE OF SPONSOR AND FUNDER	5
ROLES & RESPONSIBILITIES OF STUDY STEERING GROUP	5
PROTOCOL CONTRIBUTORS	6
KEY WORDS	6
LAY SUMMARY	6-7
STUDY FLOWCHART	8
SECTION	
1. BACKGROUND	9
2. RATIONALE	11
3. THEORETICAL FRAMEWORK	12
4. RESEARCH QUESTION/AIM(S)	13
5. STUDY DESIGN and METHODS of DATA COLLECTION and DATA ANALYSIS	13
6. STUDY SETTING	21
7. SAMPLE AND RECRUITMENT	21
8. ETHICAL AND REGULATORY COMPLIANCE	23
9. DISSEMINATION POLICY	26
10. REFERENCES	29

STUDY SUMMARY

Study Title	Fighting fatigue in the NHS ambulance workforce: development, acceptability and feasibility testing of a comprehensive fatigue risk management system to improve staff and patient safety
Internal ref. no. (or short title)	**CATNAPS**: **C**o-producing an **A**mbulance **T**rust **N**ational fatigue risk management system for improved Staff **A**nd **P**atient **S**afety
Clinical Phase	Not applicable
Study Design	Multi-site, multi-method
Study Participants	Staff in NHS Ambulance Trusts, professional stakeholders, patients with experience of ambulance services
Planned Size of Sample (if applicable)	Workshop n=60 Senior leadership interviews n=18 staff Observational ethnography n=4 NHS Ambulance Trusts Patient interviews n=15 Implementation guidance testing n=4 Trusts
Follow up duration (if applicable)	N/A
Planned Study Period	30 months: 1 October 2021 to 31 March 2024
Research Question/Aim(s)	Aims: The aim is to develop a comprehensive fatigue risk management system for the UK NHS ambulance sector that is underpinned by a theory of change and is acceptable, feasible, and likely to improve patient and staff outcomes. Objectives: 1. Co-produce an agreed set of evidence-based and emerging components of a FRMS for the UK ambulance sector that are considered feasible and acceptable. 2. Identify which components of a comprehensive FRMS are in use and why (promotors/inhibitors). 3. Investigate how front-line staff and patients experience current fatigue actions and potential to improve safety culture and reporting. 4. Development and usability testing of the FRMS and its implementation guide that allows tailoring to organisational and local context and is underpinned by a new theory of change and logic model.

FUNDING AND SUPPORT IN KIND

FUNDER(S)	FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN
NIHR	£641,528
ARC NIHR East of England	In-kind infrastructure support (communications and media)

ABBREVIATIONS

AACE	Association for Ambulance Chief Executives
FRMS	Fatigue Risk Management System
HEE	Health Education England
HSE	Health & Safety Executive
NPT	Normalization Process Theory
OHID	Office for Health Improvement and Disparities
SWAP	Supporting Wellbeing of Ambulance Personnel Study
WP	Work Package

ROLE OF STUDY SPONSOR AND FUNDER

University of East Anglia (UEA) is the sponsor of this study as the employer of the Chief Investigator. NHS Norfolk and Waveney CCG are the contracting organisation where the Chief Investigator holds an honorary contract. UEA will undertake all sponsor responsibilities outlined in the funding contract.

ROLES AND RESPONSIBILITIES OF STUDY STEERING GROUP

Study Steering Committee (SSC): will be established following NIHR guidelines, members including the independent Chair and members approved by NIHR.

Project Management Group (PMG): The PMG will be chaired by Sanderson as the Chief Investigator, and include all co-applicants and directly employed staff. This group will meet monthly beginning at Month -2 to ensure timely contracting and ethics approvals are put in place. The Group will ensure progress against milestones and manage any issues as they arise. The team will meet virtually. The PMG will provide mentorship in project management to more junior staff and provide an opportunity to lead research for partners outside of academic research. Our model of co-leads of WPs provides leadership opportunities in a supportive environment for our co-leads earlier in their career or newer to research.

Study Advisory Group (SAG): Given the scope and scale of this project, we will establish a broader Study Advisory Group which includes Work Package Research and Practice Leads from the Project Management Group, PPI team members, select Collaborators from key partner organisations, and additional stakeholders from the ambulance and health sector including College of Paramedics, unions (Chair of National Ambulance Strategic Partnership Forum), and NHS Employers. Our Study Advisory Group will meet 3 times per year, to ensure we are advised of any emerging threats to project completion, and likewise, of any emerging opportunities for maximising engagement and impact with the project as it progresses.

PROTOCOL CONTRIBUTORS

The protocol was initially drafted by Kristy Sanderson, Colleen Butler, Julia Williams, and Lucy Clark, and revised with expert input from co-investigators/research team members Sandra James, Jeremy Dearling, Jon Rogers, Bryony Porter and Chiara Lombardo.

viii. KEY WORDS

fatigue; sleep; ambulance; workplace; safety; wellbeing

ix. LAY SUMMARY

The consequences for patients of being attended to by ambulance crews suffering the effects of poor sleep and fatigue can be tragic, yet exhaustion through poor sleep quality is recognised by the NHS. Insufficient and disturbed sleep carry implications for resource management due to staff sickness and absenteeism, and for the quality of the service provided. There are many actions that staff and ambulance services can take to prevent fatigue, and to minimise its impact. Ambulance services are trying out different ways of working to help staff feel less tired at work and safer on scene, including improving rostering, but these actions are often piecemeal and we don't know how they compare against international best practice or whether they are making care and working environments safer.

What we have done so far:
Through a review of all available evidence, we found no published research studies of sleep in UK ambulance staff and only one small study on fatigue. In 2019 we conducted the first such study in the UK, collecting data from 689 staff in one Trust. We showed that: 60% of staff reported clinically important levels of mental and physical fatigue, 75% of staff reported poor sleep quality, and fatigued staff were more likely to report being injured and to feeling unsafe at scene. Looking nationally, we found that no NHS ambulance trust in England had a fatigue management policy for their staff and only four Trusts mentioned support for better sleep in staff wellbeing policies. When we presented these findings to all the Chief Executive Officers and Chair Boards of NHS ambulance services in the UK there was strong support for evaluating what ambulance services could do differently to reduce staff fatigue, improve sleep, and support patient safety.

We have brought together a team of patients, staff with lived experience, fatigue experts, ambulance service researchers and managers, international expertise, and companies currently working with ambulance services on fatigue management. We aim to develop a new approach to fatigue management for the UK ambulance sector that meets the needs of staff and operations and is most likely to improve patient and staff safety. Our recommendations will include learnings from the current COVID-19 pandemic.

To do this we will:

- Define the actions ambulance services should be taking to monitor and respond to tired crews, and help staff sleep better. We will do this by learning from what happens in other countries, and in high risk industries in the UK (Work package 1)
- Talk to senior managers on how fatigue is currently managed (Work package 2)
- Talk to front-line staff and patients to understand their experiences of current fatigue management actions and how they might impact on safety outcomes (Work package 3)
- Produce and test a guide for ambulance services on how to implement best practice in their setting that matches their needs and risks (Work package 4).

We anticipate the following outcomes:

- New knowledge on the best strategies that ambulance trusts can use to help staff sleep better and to reduce the risk of being dangerously fatigued at work

- An understanding of how patient and staff safety might be improved with a system-wide approach to preventing and managing fatigue
- A plan that can be put into practice that can be flexible enough to meet the different needs of each ambulance trust, giving a means by which we can monitor how much the new plan is costing the services, and how effective it is at reducing fatigue.

STUDY FLOWCHART

Month 1-3

Project set-up

- -2 to 0 months prepare HRA/IRAS application
- Update systematic reviews for new trials since grant submission (WP1)
- Collate any new NHS ambulance service fatigue policies (WP2)
- Horizon scanning for emerging fatigue and sleep interventions (WP1)

Month 4-14

Work Package 1: Co-produce a comprehensive FRMS for the UK ambulance sector

- Finalise FRMS coding framework
- Collate longlist of components
- Pre-workshop survey, workshop
- Report, staff/manager webinars with HSE, NHS Employers case study on co-producing a FRMS, journal article

Work Package 2: Identify which components of a comprehensive FRMS are in use and why (promoters/inhibitors)

- Update policy document analysis
- Interviews with Trust leadership
- Analysis, develop theory of change, sense-check with participants
- Briefing paper for AACE Council - Trust CEOs/Board Chairs

Month 14-22

Work Package 3: Investigate how front-line staff and patients experience current fatigue actions and potential to improve safety

- Purposive selection of four Trusts for comparative case study analysis, HRA/IRAS update and site approvals
- Staff interviews and ethnographic observation to investigate experience of current fatigue actions and organisational norms in safety incident reporting for incidents and near-misses
- Patient interviews to investigate views on proposed FRMS safety outcomes and strategies, including publicly visible fatigue countermeasures (e.g. napping on shift)
- Analysis, refinement of theory of change, sense-check results with participants

Month 20-30

Work Package 4: Development and usability testing of FRMS

- Synthesis of findings from Work Packages 1-3, triangulation of data on safety incident culture, recommendation for use as a routine outcome for change in fatigue practices
- Develop draft Implementation Guidance with Ambulance Q improvement network
- 4-month usability testing in four case study Trusts and testing of theory of change
- Finalise Implementation Guidance
- Impact outputs including case studies for NHS Employers and NHSE/I, masterclass webinars for line managers/staff, recommendations for College of Paramedics curricula guidance for HEIs, social media content, PPI-designed dissemination to patients and public
- Preparation of NIHR report and journal articles

STUDY PROTOCOL

1. BACKGROUND

Poor sleep and fatigue are common in acute and emergency health care staff (1-5). From international evidence fatigued paramedics were twice as likely to be injured on shift, 1.5 times more likely to experience a medical error and over three times more likely to engage in safety-compromising behaviours (3, 4). High-speed driving and decision-making in unpredictable environments are additional risks, which may be heightened in rural regions due to longer driving times and distance from acute hospitals (6, 7). We conducted the first substantive research of sleep and fatigue in a UK ambulance workforce, SleepSmart, funded by NIHR ARC East of England (EoE) (8), observing similarly high levels of fatigue (60% Chalder Fatigue Scale) and poor sleep quality (75% Pittsburgh Sleep Quality Index) as these international studies, and similarly strong association with self-reported safety risks. In England we found six ambulance Trusts had a rest break policy but none had a fatigue management policy, and only four Trusts mentioned sleep health in staff wellbeing policies (9). This work was done prior to the pandemic, illustrating that fatigue and poor sleep were already prevalent before COVID-19.

Fatigue is a physiological state of reduced mental or physical performance (10) and has long been recognised as a cause of incidents in safety-critical industries such as aviation and transport, resulting in multi-component prevention systems (11, 12). Health care is also a safety-critical industry, but these systems-based approaches to fatigue are not routine in the NHS (11). One of our SleepSmart participants commented in a qualitative interview: "*Other workplaces actively get their staff to consider their fatigue levels, like the airline industry*" (Hazardous Area Response Team paramedic). Front-line staff report inertia in fatigue management reform despite high-level policy support (13). An obvious strategy is improved rostering that takes into account personal preference and aims to minimise impact on wellbeing. But these worthy goals are regularly challenged by staff shortages, unplanned absences, and winter/pandemic pressures. Smart rostering on its own will also not eliminate fatigue, given the range of other factors that impact on fatigue that are not necessarily related to shift pattern. These include sleep disorders, mental health conditions, chronic pain, menopause, other physical health conditions, lifestyle habits, and mental and physical workload.

There have been few attempts to research systemic influences on paramedic practice and safety (14). Improving safety is a priority for the NHS (15), including in the ambulance sector where it was rated in the top 10 performance and quality outcomes by patients (16). The NHS ambulance sector, via the Association for Ambulance Chief Executives (AACE), has identified staff fatigue and sleep health as a priority area. With AACE we have developed this proposal through consultation with: the AACE National Council of Chief Executive Officers and Board Chairs of UK NHS ambulance services; the Quality, Governance and Risk Directors Group; the Human Resources Directors Group; and the National Ambulance Strategic Partnership Forum including trade unions and NHS Employers. All agreed on three priorities: i) agreement on what best practice in fatigue management looks like (what should we be doing?); ii) evidence on current activities compared to best practice (what are we doing?); and iii) exploring ways to link actions to improvements in safety and patient outcomes (what difference will it make?). Our patient and staff lived experience team members ratified these priorities and have informed the research plan (see below).

The risks to staff and patient safety can be reduced through development and implementation of a fatigue risk management system (FRMS). A FRMS is a complex intervention of context-tailored actions categorised as predictive, proactive, or reactive (10, 17):

Predictive actions optimise rotas to minimise circadian disruption often using biomathematical models to predict peak fatigue levels.

Proactive actions include sleep education and facilitating access to sleep disorder programs (e.g. *Sleepio*) and for other health conditions that affect sleep. Even with both predictive and proactive actions staff can arrive on shift fatigued or develop fatigue on shift.

Reactive actions include monitoring of fatigue in self and co-workers through subjective (self-report) and objective (e.g. psychomotor vigilance task) means, and countermeasures such as napping on shift.

What might a FRMS look like? While rotas are an important consideration for an FRMS, and one of the most contentious areas for changing practice as noted in our consultations with senior ambulance trust leaders and staff representatives including trade unions, an FRMS is much more than this. Predictive approaches relating to the use of biomathematical models to estimate fatigue risk associated with different shift schedules will form part of our evaluation of FRMS components, but only part. We equally value the proactive (e.g. sleep health interventions) and reactive (e.g. fatigue monitoring) components of an FRMS, and will be spending considerable effort understanding how to make these components work in practice and in synergy. For example, the proactive Alertness Consideration Tool originally designed for the aviation industry (Energy Institute, 2014) takes its users through a series of questions relating to alertness, sleep, actual shift times and the demands of tasks on shift and enables a meaningful conversation around broader sources of fatigue. Reactive measures relating to how to include the consideration of fatigue in accident/incident investigations will also be drawn from other industries. It is notable that we are including sleep health in this project, taking a health promotion approach that considers the physical and mental health causes of poor sleep and fatigue and the opportunities for primary prevention of work-related sleep disruption through inclusion of sleep hygiene education approaches, particularly important for paramedic science students and newly qualified professionals. To contextualise to the NHS ambulance sector, an illustrative FRMS might include: smart e-rostering systems with additional personalisation to match individual preference and chronotype (predictive strategies); chronic poor sleepers signposted to sleep health interventions and education in good sleep habits available to all (proactive strategies); safe, brief napping and the policies and facilities to do so available and supported by line managers, colleagues, and patients and the public (reactive strategies).

While some elements of a FRMS are in use within the NHS, implementing a comprehensive FRMS represents a step-change in safety science practice for the NHS (11). The FRMS approach of linking patient safety and staff wellbeing into a cohesive strategy supports the NHS workforce vision of a responsive work environment that promotes physical and mental health, and evidence-based rostering (18). In terms of supporting sleep health for staff, during COVID-19 poor sleep has been amongst the top reasons for staff accessing support and the most popular content in the freely provided app Headspace. For evidence-based rostering, the NHSE/I and NHSX Releasing Time for Care Program has recently allocated £26 million across 68 acute and community Trusts to help introduce e-rostering (DHSC press release 15.01.21), part of the NHS Long Term Plan for all shifts to use e-rostering across all shifts for doctors, nurses, Allied Health Professionals, health scientists and pharmacists by the end of 2021. This investment in digital infrastructure is making the NHS ready for future rostering innovations, such as tailoring to personal characteristics and chronobiology.

In terms of fatigue mitigation strategies, the NHS/Health Education England (HEE) Mental Health Commission highlighted the importance of providing facilities for rest and napping. The British Medical Association's (BMA) Fatigue and Facilities Charter includes provision of "an easily accessible mess with appropriate rest areas 24 hours a day, seven days a week,

allowing staff to nap during breaks" and "sleep facilities available free of charge for all staff who are rostered or voluntarily resident on-call at night." The NHS has invested £10 million to provide rest facilities in hospitals for junior doctors, which in some Trusts are being extended to consultants and other health professionals. These policy actions are supported by staff-led initiatives such as #fightfatigue, an awareness and educational campaign started by the Royal College of Anaesthetists following the death of one of their members in a car accident while driving home after a night shift. The campaign aims to change the culture of fatigue management in hospitals to improve staff and patient safety. It has support across the NHS workforce having been endorsed by the BMA, Royal College of Midwives, the College of Paramedics, Royal College of Emergency Medicine, the Patient Association, and HEE.

2. RATIONALE

What "fighting fatigue" in the NHS ambulance sector would look like has not been investigated. This project will address this gap and provide some initial evidence on association with staff and patient outcomes. Our patient-focussed, consensus-building approach will be applicable to other non-hospital settings including community-based health and social care that operate 24 hours across diverse locations. No NHS Trust in any sector has implemented a FRMS, although some components may be in use such as nap rooms (11). Amongst NHS Ambulance Trusts the most mature strategy we have identified is by the Scottish Ambulance Service.

Our systematic evidence map (19) located only one small qualitative study on fatigue and no studies on sleep in UK ambulance staff. We then conducted a search for registered studies, systematic reviews, large trials, and grey literature on fatigue risk management and sleep health promotion, and their implementation, in emergency medical care and other health and safety-critical settings. For the ambulance sector the most relevant body of evidence comes from a national programme of work to develop guidance on fatigue risk management for the emergency medical services sector in the United States led by collaborator Patterson (20) and underpinned by systematic reviews. The systematic reviews showed that (n of studies): there was some evidence that fatigue education training with shift-workers (n=18) improved patient and staff safety and sleep quality and reduced feelings of fatigue, stress and burnout but study quality was generally low and the optimal components of a FRMS remain unknown (21); 8 versus 12 hour shift durations (n=38) had mixed findings, with some evidence showing improved staff and patient safety for shorter shifts but other outcomes favoured longer shifts and study quality was generally low (22); moderated caffeine intake in shift workers (n=8) improved psychomotor performance and vigilance but there was some risk of reduced sleep quality (23); napping on shift (n=13) reduced sleepiness but did not improve reaction time (24); only one study of biomathematical shift scheduling in shift workers was located, where vehicle accidents in truck drivers was reduced (25). Other recent reviews including a Cochrane Review have reached similar conclusions (26-28). Work is underway to inform fatigue management in the NHS acute hospital sector through surveys to understand fatigue in doctors [5, ISRCTN21869845] and an improvement project in a labour ward in one hospital which is using Normalisation Process Theory to guide staff in co-designing fatigue management strategies [ISRCTN84326878]. A NICE Clinical Knowledge Summary for shift-workers recommends a range of preventive and remedial strategies, largely drawing on the work of Collaborator Patterson cited above, but notes a lack of evidence on implementation.

In summary, the evidence suggests individual components of a FRMS which may be effective, but we do not yet know about the optimal packaging of these interventions (21). Theories of change for FRMS in any sector are rare, and FRMS adoption in the NHS needs local tailoring and understanding of barriers and facilitators (26).

3. THEORETICAL FRAMEWORK

All Work Packages as described below will be guided by Normalisation Process Theory (NPT) (30) and use of the NoMAD tool (31), to help map the individual, operational and contextual considerations for FRMS components and potential promoters and inhibitors. NPT can help in designing a complex intervention by describing the resource, human behaviour, and system changes that will be required (32). It can also be used as a tool to guide selection of the individual components of a complex intervention (32). NPT is still a theory under development, and we are using it as an aid to think about implementation rather than a “conceptual straight jacket” (33). We are already using the NoMAD as a guide in an NHSE/I-funded project to develop implementation guidance for new suicide prevention guidance for the NHS Ambulance sector. The NoMAD tool was perceived to have face validity and being straightforward to apply with different stakeholders involved in implementation (frontline staff, line managers, senior managers, charities providing services to the NHS Ambulance sector).

Integration with existing policies, practices and systems will be done through our existing relationships with senior leadership groups that are co-ordinated by Association for Ambulance Chief Executives (AACE) with Collaborator Anna Parry: the HR Directors Forum (Collaborator Kerry Gulliver, Director of Human Resources & Organisational Development, East Midlands Ambulance Service), and the Quality, Governance and Risk Directors Group (Collaborator Andrew Parker, Scottish Ambulance Service). These networks support UK-wide development and implementation of strategic priority areas and allow sharing of current policies and practices. Across the project our definition of “expert” encompasses experts by experience, and is inclusive of patients and public, staff with lived experience of fatigue and its consequences, and implementers of fatigue mitigation and sleep health support strategies for 24-hour workforces.

Table 1 provides an illustration of how NPT constructs and sub-constructs are used throughout the WPs to guide component selection and implementation feasibility testing. We use the example action of “napping on shift”. Napping is an evidence-based reactive fatigue strategy that is being promoted in some sectors of the NHS (e.g. NHSE/I funding for nap rooms in acute hospitals) and anecdotally has huge variation in acceptability and use within the ambulance sector.

Table 1: Illustration of how NPT constructs and sub-constructs via NoMAD are being applied throughout the WPs to capture perspectives of different users using napping as an example.

	Constructs with example sub-construct items from NoMAD			
	Coherence	Cognitive participation	Collective action	Reflexive monitoring
WP1: prioritisation of evidence-based actions that are considered acceptable and implementable	Internalisation: .. see the potential value of napping for my work	Legitimation: .. believe that napping is a legitimate part of my role	Skill set workability:.. sufficient training .. provided	
WP2: identify gap between current and ideal FRMS actions and possible reasons behind this	Communal specification: … shared understanding of its purpose	Initiation: .. key people who drive the intervention forward and get others involved	Contextual integration: Management adequately support napping	
WP3: Constructs will guide interview topics and observation guide	Differentiation: .. can see how .. napping differs from usual ways of working	Enrolment: .. open to working with colleagues in new ways	Interactional workability: .. easily integrate napping into existing work	
WP4: design implementation strategy and guidance: pre-post NoMAD during feasibility stage for FRMS as a whole and selected components			Relational integration:… disrupts working relationships	Individual appraisal: .. value the effects napping has had on my work

4. AIMS AND OBJECTIVES

The aim is to develop a comprehensive FRMS for the UK ambulance sector that is underpinned by a theory of change and is acceptable, feasible, and likely to improve patient and staff outcomes.

Objectives:
1. Co-produce an agreed set of evidence-based and emerging components of a FRMS for the UK ambulance sector that are considered feasible and acceptable.
2. Identify which components of a comprehensive FRMS are in use and why (promotors/inhibitors).
3. Investigate how front-line staff and patients experience current fatigue actions and potential to improve safety culture and reporting.
4. Development and usability testing of FRMS and its implementation guide that allows tailoring to organisational and local context and is underpinned by a new theory of change and logic model.

5. STUDY DESIGN and METHODS of DATA COLLECTION and DATA ANALYSIS

Four Work Packages (WPs) address each Objective in turn. The workflow, WP outputs, and impact activities are depicted in the Flow Chart. This proposal forms part of the lead applicant's research programme as ARC EoE Deputy Theme Lead for Mental Health and workforce wellbeing lead. As part of our commitment within the ARC to diversity and inclusion in research, we will work with relevant ambulance sector networks such as the

National Ambulance BME Forum to ensure diversity in participation and representation across the WPs, as the burden of shift work and poor sleep health, or risk factors thereof, may fall unequally on certain groups.

Work packages 1 and 2 are covered by IRAS 308115 (approved 07 July 2022).
Work packages 3 and 4 are covered by IRAS 316598 (pending).

Design

We will conduct a multi-site, multi-method study with four Work Packages (WPs). This non-experimental methodology is appropriate given that a FRMS for the ambulance sector is a complex intervention under development (29), with some individual components already implemented or under active consideration. The project will run for 30 months:

Work Package 1
Research Leads: Prof Kristy Sanderson and Dr Lucy Clark, UEA
Practice Leads: Dr Colleen Butler, Health & Safety Executive
Objective 1. Co-produce an agreed set of evidence-based and emerging components of a FRMS

Work Package 2
Research Leads: Prof Kristy Sanderson and A/Prof Sandra James, UEA/OHID
Practice Leads: Fay McNicol, Head of Health & Safety, Scottish Ambulance Service
Objective 2. Identify which components of a comprehensive FRMS are in use and why

Work Package 3
Research Leads: Prof Julia Williams, University of Hertfordshire/South East Coast Ambulance Service NHS Foundation Trust, and Dr Chiara Lombardo, UEA
Practice Leads: Jeremy Dearling and Jonathan Rogers
Objective 3: Investigate how front-line staff and patients experience current fatigue actions and potential to improve safety culture and reporting

Work Package 4
Research Leads: Prof Julia Williams with NIHR ARC EoE Implementation team
Practice Leads: Ambulance Q Network
Objective 4. Development and usability testing of FRMS and its implementation guide

Data collection and analysis

Work Package 1

A modified Delphi approach will be used that includes both a survey and virtual co-design workshop, and reported following best practice guidelines (34, 35). Experts include staff with lived experience of fatigue and its consequences, and implementers of fatigue mitigation and sleep health support strategies for 24-hour workforces. The following steps will be followed:

i) led by co-applicant Butler, finalise a coding framework for identifying candidate best practice FRMS components, with the framework based on existing HSE resources and international examples (12) including by collaborator Patterson (20). The coding framework will consist of a spreadsheet to synthesis and summarise information relevant to implementation for each potential FRMS component from the perspective of decision-makers and using a rapid review approach (focus on most important outcomes and identifying what evidence threshold has been met): the level of evidence from systematic reviews to case studies from industry or practice (including from Collaborators Gee and Eden and ambulance Trusts); cost; usability; level of training and competence required for

implementation; and any application to date in ambulance, emergency, health care, or defence settings. Narrative summaries of implementation potential are informed by NPT constructs and presented in four criteria: existing use in the ambulance or related workforces (health, emergency services, defence); usability; knowledge needed to use/training; and cost (implementation cost and economic evaluation evidence). Our starting point is the existing evidence base, but we are also forward thinking in our approach by including horizon-scanning of novel and emerging strategies. It is prudent to give due attention to evidence-based strategies that could be implemented now, and to seek to understand why they haven't as yet been implemented (or implemented sporadically) and how to maximise their potential impact. HSE's experience of working across industry including rail, aviation and energy sectors will enable the team to draw on knowledge of their emerging and mature FRMS components. The co-produced FRMS will have the flexibility to incorporate future innovations in fatigue and circadian science, and we will have established a prioritisation and evaluation framework to understand the impact and value of an FRMS. Screening will be conducted independently by two reviewers. The coding framework will be piloted for five components with three reviewers and criteria with disagreements, if any, refined. For all data extraction, where a reviewer is unclear if the evidence threshold has been met it will be resolved by discussion amongst the research team.
ii) This framework will be used to generate a longlist of potential FRMS components. Eligibility for inclusion in the longlist is based on a minimum threshold of relevant research or practice evidence of improving or preventing fatigue and/or sleep or related performance outcomes (e.g. safety, lost productivity). A component may therefore be included in the longlist on the basis of research or evaluation evidence in any occupational setting, and/or on current use in an ambulance, health or related setting. For research-based evidence the highest level of evidence met will be recorded using the CEBM (2009) hierarchy from 1a (systematic review of RCTs) to 5 (expert opinion without critical appraisal such as industry guidance without outcome data). Risk of bias of systematic reviews of interventions is assessed with ROBIS, with one reviewer checking ROBIS assessment for the other two reviewers (Whiting et al, 2016; Pieper et al 2019). For this applied occupational health context the fourth level of evidence (patient case series) will be replaced with case studies from practice/industry. The credibility of case studies as research evidence will be based on the organisational case study reporting standards developed by Rodgers et al (2016). Evidence will be restricted to last 5 years to ensure it is contemporary and relevant to modern workforces. We are erring on the side of inclusion for the longlist to ensure that any potentially applicable FRMS components are brought forward for consideration in the design workshop. Examples of such approaches include: matching rota scheduling to an individual's chronotype (*predictive*) (36); devices to reduce circadian misalignment and improve sleep quality such as bright light therapy delivered by safety-style glasses that can show improvement in a matter of days (*proactive*) (37); and real-time alertness monitoring such as very brief psychomotor vigilance tests delivered by smart phone (*reactive*) (38). Evidence summaries for each component will be written up in a draft report to be circulated prior to the co-design workshop.

iii) distribute a brief online survey of the brief NoMAD measure (31) to stakeholders who would be involved in implementation to capture implementation capacity, inhibitors and promoters for each action (Appendix). The draft report will be distributed with the survey. NoMAD items are modified slightly to be appropriate to implementation planning, and will address the constructs relevant to Work Package 1 as shown in Table 1. The survey platform Online Surveys (Jisc) will be used. NoMAD data will be used as an aid to indicate whether any of the longlist appear unacceptable or "unimplementable" at this stage, based on a median score of 5 or less in at least half of the NoMAD items within each of the constructs. We will conduct a sensitivity analysis on this threshold, as there is no consensus on how NoMAD items should be scored or applied in practice (31). These "unimplementable" approaches will be summarised in the FRMS development documentation alongside what would need to change to make these acceptable/implementable, but will not be considered

further. The longlist of candidate strategies will be summarised in a report distributed to workshop attendees 2 weeks in advance to set the context for the consensus meeting that will use the World (Knowledge) Café approach.

iv) prioritise this longlist of candidate strategies over a workshop in 2022. This will be held virtually. In addition to the full research team including PPI co-investigators and collaborators, invited stakeholders will include Ambulance Trust Directors of Quality and Risk, Operations, and Human Resources, commissioners, occupational health practitioners and Society for Occupational Medicine, NHS People Directorate, trade unions, College of Paramedics, AACE, OHID, staff with lived experience of fatigue consequences, and invited fatigue researchers. The event will be capped at 60 participants (Appendices 3,4– workshop invitations). The event will be hosed on MS Teams (HSE) and using a subscription version of MURAL (Team+, GDPR compliant) for the interactive and decision-making elements. Consent for use of written material generated during the workshop to be used in research and research outputs is included at point of study registration. This written material will include notes, comments, annotations on the online whiteboard, and anything noted in the chat function. Any identifying material (such as in chat) will be deidentified prior to analysis and codes assigned to individuals. The workshop will not be audio recorded to encourage free discussion. This workshop will consist of 2x2.5 hour sessions where stakeholders will review the longlist and NoMAD findings, to define a final list of acceptable, feasible and potentially impactful actions. Together these actions comprise the first version of the FRMS. We will use the World or Knowledge Café approach during the workshops: Butler has used this approach in HSE workshops with industry on fatigue management to co-design FRMS in various sectors (39, 40); Sanderson has used this approach in research projects to co-design and prioritise elements of a complex intervention in workplace health delivered to a workforce of approximately 30,000 staff (41) and to prioritise actions for a national workplace mental health consensus statement (42). Butler's extensive experience in FRMS design workshops prepares us for the potentially emotive and divisive potential of such work. World Café encourages a decision-focussed and respectful space for collaborative dialogue across diverse and possibly contradictory perspectives. The structure of the workshop is presented in Appendix and is as follows:

Session 1: small break-out groups will discuss and vote on the longlist options, with virtual rooms hosted by two members of the research team. Participants will cycle through two "tables" (virtual rooms) and the host will guide discussion to iteratively refine the candidate strategy list. The cycles of discussion will focus on the implementation constructs identified through NoMAD, including fits with ways of working [Coherence], staff buy-in [Cognitive Participation), and training and resources [Collective Action]. Session 1 will discuss two groups of candidate components.

After Session 1 the research team will integrate the decisions to present at the start of Session 2 on the following day.

Session 2: Cycles of discussion will consider a second set of two groups of candidate components, then we will review the prioritised FRMS components and discuss and decide on strategies where consensus has not been reached. This will also provide a final opportunity to reflect on the FRMS in its totality, any considerations around sequencing or co-dependencies of selected actions, and the implementation considerations identified through NoMAD findings and iterative discussion.

iv) write a report and distribute to workshop and survey contributors. Prepare other dissemination outputs through our networks including webinars delivered by HSE for managers and staff, a NHS Employers case study on co-producing a FRMS linking staff wellbeing strategy to operations, and via a journal article.

Outputs: a co-designed FRMS tailored to the NHS ambulance sector, webinars, NHS Employers case study, journal article

Work Package 2

We will update our document analysis of fatigue-related policies to capture any new developments since our research (April 2020) (9). At each NHS Ambulance Trust we will invite Quality & Risk Directors, Operations Directors, Clinical Leads, and Human Resources/Wellbeing Leads (or nominees) for a 45-minute semi-structured interview by virtual method of choice (Teams/Zoom/phone) to explore current implementation of best practice FRMS components identified in Work Package 1. People in these roles will have been previously contacted about Work Package 1 and may have participated, and information on the post-workshop interviews (Work Package 2) was included at time of Work Package 1 recruitment. This information will be re-circulated by R&D teams to people in relevant roles. At a minimum we will aim to interview at least one senior leader per Trust, anticipating a total of 18 interviews. Collaborators Parry (Governance, Wellbeing), Gulliver (HR) and Parker (Quality & Risk) will guide recruitment of appropriate roles in each Trust who bring sufficient oversight of current fatigue management-related actions. This purposive sampling approach will help us obtain maximum variation in perspectives of fatigue management across institutional departments and roles. We will use our NoMAD and workshop findings to develop an interview topic guide to capture actions and implementation successes and challenges and associated promoters/inhibitors, and perceived or evidenced impact on outcomes for staff (e.g. absence) and system (e.g. costly incident investigation) (Appendix).

Interviews will be conducted by core research team members including the Study Manager, Sanderson and James. We will ask interviewees which elements of FRMS are in place; how these are operationalised; the barriers and facilitators of implementation; other policies, protocols, SOPs that are employed to manage fatigue; how FRMS/other policies are practised/adhered to, impact on staff and incident reporting; and recommendations for improving and optimising implementation of FRMS. Rogers will contribute his expertise as a paramedic with lived experience of the consequences of fatigue. Drawing on Butler's extensive experience in fatigue attribution and causal investigation, we will probe if and how the role of fatigue is investigated in these incidents. We will also ask about specific actions taken during the COVID-19 surge(s), or initiatives that were paused.

In our consultations for this proposal the AACE Quality, Governance and Risk Directors Group identified vehicle accidents and drug administration errors as the safety incidents most likely to be improved through better fatigue and sleep management. However they expressed concern in consistency of reporting and recording of these outcomes and hence ability for use in routinely tracking impact of fatigue reform. These senior staff will be asked about coding practice of incidents and near-misses with Datix, which is the safety incident reporting database used by all Trusts. Interviewees will be asked to reference their Trust's monthly aggregated Datix data from the previous 12 months to help prompt reflections.

Interviews will be recorded via the virtual platform (Teams, Zoom), transcribed (Transcript Divas (Limited)), and analysed in NVivo using thematic analysis. Each interviewee will be sent their own transcript for review. From WPs 1 and 2 will we develop an initial theory of change with logic model (43) for the FRMS implementation guided by issues raised through application of NPT.

Outputs: identification of which FRMS components are currently in use across all NHS Ambulance Trusts, reasons for use, and perceived or potential impacts including vehicle accidents and drug administration, and draft theory of change and logic model.

Work Package 3
[Draft subject to HRA/REC approval]

We will use comparative case study analysis with interviews and observations, to explore how staff publicly (patient-facing) and privately (non-clinical time like rest breaks) manage any tiredness on shift and respond to any near-misses or incidents (44). Based on the findings of WP2 we will purposively select (45) four Trusts representing a range of fatigue risk management maturity (from more developed to less developed) and including at least one non-English Ambulance Trust. We are particularly interested in exploring/observing the reactive FRMS strategy of napping that is promoted in the NHS but from our SleepSmart study and AACE consultations acceptability and facilities vary widely. We will also explore consistency in near-miss and incident reporting and local norms in recording fatigue as a contributing factor. Recruitment will be co-ordinated through each Trust's R&D team. Each case study Trust will be supported by funded time for a research paramedic through the Trust's R&D team, to co-ordinate site participation and support recruitment. Interviews will be primarily conducted by the WP3 research team, with observations conducted by the WP3 observation team with assistance of site research paramedics.

Interviews: From WP2 insights including around Datix data we will select three stations and one Emergency Operations Centre (EOC) per Trust and invite local area managers and front-line staff to participate in individual semi-structured interviews. We anticipate about 3xTeams/Zoom/phone interviews per location, to give 12 interviews per Trust and 48 interviews in total. The interview guide will be an adapted version of that used in WP2 to explore awareness/engagement/impact of current fatigue actions (predictive, proactive, reactive), and using aggregated Datix safety incident data as a prompt for reflecting on safety culture. A draft interview topic guide will be refined following the first two work packages (Appendix).

We will interview up to 15 ambulance service patients via Teams/Zoom/phone to get views on the proposed FRMS safety outcomes and strategies, including publicly visible fatigue countermeasures (e.g. napping when in a parked vehicle), with the semi-structured interview topic guide overseen by PPI co-applicant Dearling. We have included costs for translation/interpretation of materials/interview where needed, with interviews anticipated to take approximately 45 minutes. An interview topic guide is provided (Appendix).

Observations: From these interviews we will recruit one station and EOC per Trust (2x4 Trusts=8 sites) for trained non-participant observers (WP3 team members and research paramedics at each trust) to accompany ambulance crews/EOC staff on a run of 4 consecutive shifts, typically 2 day and 2 overnight shifts, and including one weekend shift where possible. We will work with each Trust R&D office to identify stations and EOCs that have capacity to participate, to manage burden from other potential research studies that may be running. Shifts typically last 12 hours, but can also be 8 or 10 hours. Including observation for up to 1 hour before and after shift, this gives a total of up to 448 hours of observation (per Trust is 2 sites x 4 shifts x 14 hours= 112 hours maximum). Consecutive shifts will allow observations at beginning, during, and end of a run of nights. Including pre- and post- shift will capture preparatory and wind-down actions. Including an EOC site ensures inclusivity of different types of front-line work, the importance of which is illustrated in this quote from a SleepSmart study participant: "*For call handlers on day shift…11 hours of taking non-stop calls is tough…we can actually have a huge impact on the health and safety of the patient if we are fatigued*" (EOC call handler). We have allowed a 6-month period to conduct these observations, this allows us to stagger data collection across Trusts and also to observe practice in different seasons. This is important given seasonal influences on sleep, clinical demand, and safety risks such as road traffic incidents.

Our estimated total number of observation hours is consistent with other ethnographic observational studies in the NHS ambulance sector that have balanced practicality with rigour and generated new insights into the nature of ambulance work (e.g. 240 hours in one Trust (44); approximately 340 hours across 3 Trusts (14); 50 hours in one Trust (46)). The observation template will be informed by NPT constructs adapting an existing template (47) and drawing on ethnographic observations of ambulance crews/call handlers (46, 48, 50) (see Appendix Staff Observation Handbook). All staff to be observed will be provided with a participant information sheet and invited to consent to observation (Appendix). There will not necessarily be the same crews on the four consecutive shifts, so number of participants may be up to 8 staff. In EOCs, we will shadow one person per shift, and again this will not necessarily be the same person on consecutive shifts, so we will observe up to 4 EOC staff per Trust. For crew and EOC observations we will not record any data specifically about patients or carers/family members, and will seek verbal consent to the observer being present, where there is someone capable to do so (Appendix). Verbal consent recording and observation notes will be recorded with a tablet. Each observer will use a dedicated study tablet that will be password-protected and used solely for CATNAPS. We will record use and quality of staff rest facilities such as whether a napping space and comfortable furniture is available, and the context of any observed safety near-misses/incidents. Close proximity observation, such as in ambulance vehicles or Emergency Operation Centres (EOCs), may be particularly prone to the Hawthorne effect, where the act of observation changes behaviour. Our approach will include the six steps developed by Oswald et al (49) from a study of workplace safety-related behaviour, that seeks to minimise the Hawthorne effect by progressively building trust. This is similar to the method used by Co-Applicant Williams and colleagues in an observational ethnography study in EOCs (50) and two other ambulance sector studies (HS&DR 10/1007/53, NIHR130811), that included a day of familiarisation at each site before the series of observed shifts. Detailed field notes and reflections will be kept, with these written up within a week of the observation period where possible.

Integrated analysis: All interviews will be recorded and transcribed, and observational data transferred to NVivo. Trustworthiness will be promoted through participant review of extracted data and input to analysis by PPI co-applicants. Analyses will initially use a thematic approach to draw out themes across all data sources, with subsequent development of taxonomies of contextual (system, team, individual) influences on fatigue mitigation strategies and safety consequences (14) guided by NPT constructs. We will consider tensions between what may be best for staff and what may be best for patient safety. Analyses will inform any refinements to our theory of change and logic model.

Work Package 4
[Draft subject to HRA/REC approval]

i) We will do a final integration of findings from WPs 1-3 with collaborators and study advisers to ensure FRMS strategies are feasible to implement at Trust and station level and are likely to improve safety. We will triangulate all data pertaining to safety incident reporting to provide guidance to Trusts on how this routinely collected data may be used and/or improved to monitor the impact of changes to fatigue management practices.

ii) Working with the Ambulance Q network, a quality improvement initiative established through the Health Foundation Q Community and further developed through working with NHS Horizons, we will produce implementation guidance. The guidance will facilitate tailoring to context and prioritisation of actions, and how to increase the impact of actions already implemented or planned. We will use principles of quality guideline development for guidelines intended for workplaces (49) and draw on co-produced implementation documents produced as part of the US ambulance national fatigue project by our Collaborator Patterson (20). The guidance will include a self-audit tool to benchmark current practice against the FRMS, with information on capturing benefits to staff, patients and

system efficiency that have been identified through development of the FRMS logic model. The guidance will include recommendations on the use of routine data for monitoring of any FRMS-related changes, which may include staff experience and wellbeing such as use of staff wellbeing supports related to sleep and absenteeism, in addition to safety incident reporting as noted above. The cultural, system and resource barriers and facilitators from NoMAD and the previous work packages will be presented with suggested actions. As noted above we are used the NoMAD as a guide in an NHSE/I-funded project to develop an implementation tool for new suicide prevention guidance for the NHS Ambulance sector. We can draw on our learnings in using NoMAD for designing implementation resources for the NHS ambulance sector.

During this WP we will meet 5 times with our implementation science experts, the NIHR ARC East of England Implementation team, co-led by Professor Andrée le May and Professor John Gabbay (now handed over to Eastern AHSN to lead on implementation). The ARC EoE implementation team will advise on implementation approaches in the guidance document. Some Ambulance Trusts, such as the Scottish Ambulance Service and the Northern Ireland Ambulance Service, have fatigue working groups that lend themselves to the community of practice approach. These meetings will include exploration of how existing short- and longer-term outcomes as identified in the logic model can be measured after completion of this project, including use of routine/administrative data sets related to patient and staff experience and operational performance. We will consider existing data sources such as Datix, the annual NHS staff survey, and routinely reported staff indicators such as absenteeism and retention.

iii) Working with existing partnerships from WP3, we will go back to the four case study Trusts to determine their opinion on the usability of the guide over a 4-month period. We will invite implementation stakeholders within each Trust, including representatives from Operations, HR, wellbeing, and Quality, to complete the brief online NoMAD survey for the FRMS pre and post the feasibility testing period, adapting the survey used in WP1 (Appendices). We will aim for at least 10 survey participants per Trust. The Collective Action and Reflexive Monitoring items will be particularly informative for this purpose. Change scores for individual items will be calculated. In the post survey we will include additional items exploring which features of the implementation guidance were accessed, which were found useful, which features contributed to any change in practice or senior-level approval to plan for change in practice, and any perceived unintended consequences of implementation planning (e.g. any negative reactions from staff to proposed changes in policy or practice). Finally we will hold 90-minute online feedback session to case study Trusts, co-delivered with Ambulance Q and the ARC Implementation Leads, to allow us to discuss these findings with the four case study Trusts, and to test and make any final refinements to our theory of change and the implementation guidance. Design and reporting of WP4 is guided by the Standards for Reporting Implementation (StaRI) studies (51) as applied to a useability and feasibility testing phase.

WP4 solidifies the benefits of co-design and increases Ambulance-service ownership of the FRMS and its implementation guide. Our approach includes sense-making of potential pathways to patient and staff outcomes through our co-produced theory of change and logic model. Our approach ensures Trusts are ready for FRMS implementation should this study be successful. Our partnership with Ambulance Q ensures we are linked in with improvement and implementation teams on the front line, and this project will help facilitate and/or support locally-run “fatigue fighting” groups in the NHS ambulance sector such as has been established by the Northern Ireland Ambulance Service.

6. STUDY SETTING

Work Package 1 and 2

All stand-alone NHS Ambulance Trusts in the UK to be invited (N=13):
North East Ambulance Service NHS Foundation Trust
Yorkshire Ambulance Service NHS Trust
North West Ambulance Service NHS Trust
West Midlands Ambulance Service University NHS Foundation Trust
East Midlands Ambulance Service NHS Trust
South Western Ambulance Service NHS Foundation Trust
South Central Ambulance Service NHS Foundation Trust
South East Coast Ambulance Service NHS Foundation Trust
London Ambulance Service NHS Trust
East of England Ambulance Service NHS Trust
Welsh Ambulance Services NHS Trust
Scottish Ambulance Service
Northern Ireland Ambulance Service Health and Social Care Trust

Work Package 3 and 4

Four purposively sampled Trusts, including at least one non-English Trust. Trusts to be approached for participation are likely to include:
East of England Ambulance Service NHS Trust
North West Ambulance Service NHS Trust
Scottish Ambulance Service
South East Coast Ambulance Service NHS Foundation Trust
South Western Ambulance Service NHS Foundation Trust

7. SAMPLE AND RECRUITMENT

A summary for all work packages is provided in the recruitment flow diagram (Appendix).

Work Package 1

Directors/Leads and staff in specific roles in UK NHS Ambulance Trusts

Inclusion: Staff are eligible to participate by virtue of their professional roles and include Quality & Risk Directors, Operations Directors, and Human Resources/Wellbeing Leads (or nominees/team members), and being available to attend the workshop (held virtually over two half-days) and (optionally) complete a pre-workshop survey. We aim to involve up to 3 staff per Trust (N=39).
Exclusion: not in an eligible role, not able or willing to provide consent.
Recruitment: Ms Anna Parry, AACE Deputy Director and Study Collaborator forwards a study introduction letter to NHS Ambulance Trust CEOs, advising them of the study and what is involved for work packages one and two (Appendix). Ms Parry then forwards an email invitation (Appendix) to the AACE Work Stream Groups representing all UK NHS ambulance services (AACE work streams: Human Resource Directors, Wellbeing Leads, National Directors of Operations Group, Quality, Improvement, Governance and Risk Directors), they in turn discuss with their Trust R&D team to forward on the invitation. Directors/senior staff may also forward a survey and workshop invitation to other staff in their team who may be best placed to participate. Interested staff contact CATNAPS research team to participate via a link in the invitation email which includes the PIS and consent (Appendix).

Other professionals with knowledge

Inclusion: Staff are eligible to participate by virtue of their professional roles and knowledge of fatigue management, sleep health, or NHS people management, and being available to attend the workshop (held virtually over two half-days). We aim to involve 15-20 staff in this category. The invitation list includes stakeholders from commissioners, occupational health practitioners and Society for Occupational Medicine, NHS People Directorate, College of Paramedics, AACE, trade unions, and fatigue experts from other high-risk settings such as rail and aviation.
Exclusion: not in an eligible role, not able or willing to provide consent.
Recruitment: stakeholder invitations will be distributed via the research team's networks. Interested staff contact CATNAPS research team to participate via a link in the invitation email which includes the PIS and consent (Appendix).

Work Package 2

Directors/Leads semi-structured interviews

Inclusion: Staff are eligible to participate by virtue of their professional roles and include Quality & Risk Directors, Operations Directors, and Human Resources/Wellbeing Leads (or nominees/team members), and being available to attend a virtual interview. We aim to interview one or two staff per Trust. These staff are also approached for Work Package 1 and may have participated.
Exclusion: not in an eligible role, not able or willing to provide consent.
Recruitment: Work Package 1 information and consent material also includes information on the post-workshop virtual interview that comprises Work Package 2. The information will be forwarded by R&D teams and interested participants will contact the CATNAPS research team directly to participate. The invitation is via email and includes the participant information sheet and consent (Appendix). Study registration and consent is via an online form. Consent will be re-affirmed at the start of the interview.

Work Package 3
[Draft subject to HRA/REC review and approval]

Front-line staff interviews

Inclusion: Staff are eligible to participate by virtue of their professional roles and working in the selected station or Emergency Operation Centre, and being available to attend a Teams/Zoom/phone interview. We anticipate about 3xTeams/Zoom/phone interviews per location, to give 12 interviews per Trust and 48 interviews in total.
Exclusion: not in an eligible role, not able or willing to provide consent.
Recruitment: From WP2 insights including around Datix data we will select three stations and one Emergency Operations Centre (EOC) per Trust and invite local area managers and front-line staff to participate in individual semi-structured interviews. The study invitation will be forwarded by R&D teams and interested participants will contact the CATNAPS research team directly to participate, as we have done for Work Packages 1 and 2 (IRAS 308115). The invitation is via email and includes the participant information sheet and consent (Appendix). Study registration and consent is via an online form. Consent will be re-affirmed at the start of the interview.

Patient interviews

Inclusion: User of ambulance services within past year. We aim to interview 15 patients. We have included costs for translation or materials, and interpretation (BSL and up to 3 other languages) in interview where needed to encourage diversity amongst potential participants.
Exclusion: Unable to provide consent to a virtual or telephone interview.
Recruitment: Method of recruitment and consent will be finalised with each of the four participating Trusts in liaison with R&D team and relevant patient groups (e.g. PALS) (draft PIS and consent in Appendix). The invitation will come from PPI co-investigator Dearling. Members of groups such as PALS bring an understanding of ambulance operations and systems along with their lived experience of ambulance care, and will be involved in the study as research participants. Consent will (re)affirmed at start of interview.

Observational Ethnography

Inclusion: Ambulance station and EOC selected on advice from Trust R&D office with capacity to participate.
Exclusion: Ambulance stations and EOCs judged not to have capacity to participate.
Recruitment: We will recruit one station and EOC per Trust (2x4 Trusts=8 sites) for trained non-participant observers (WP3 team members and funded research paramedics at each trust) to accompany ambulance crews/EOC staff on a run of 4 consecutive shifts, typically 2 day and 2 overnight shifts, and including one weekend shift where possible. We will work with each Trust R&D office to identify stations and EOCs that have capacity to participate, to manage burden from other potential research studies that may be running.

Work Package 4
[Draft subject to HRA/REC review and approval]

Implementation stakeholders online survey and online feedback session

Inclusion: Implementation stakeholders in the four case study Trusts are eligible to participate by virtue of their professional roles and include staff in roles related to Quality & Risk, Operations, and Human Resources/Wellbeing Leads, and being available to complete an online survey and/or attend an online feedback session. We will aim for at least 10 survey participants per Trust.
Exclusion: not in an eligible role, not able or willing to provide consent.
Recruitment: The information will be forwarded by R&D teams and interested participants will contact the CATNAPS research team directly to participate. The invitation is via email and includes the participant information sheet and consent (Appendix). Study registration and consent is via an online form.

8. ETHICS AND REGULATORY CONSIDERATIONS

Assessment and management of risk

The major barriers and mitigation strategies are presented in the table below. We will maintain a detailed project risk register that will be reviewed monthly within the PMG and escalated to the SSC where needed.

Barrier	Mitigation strategy
Ongoing disruption from COVID19 threatens data collection	Data collection and ways of working have been designed to be virtual where possible or a contingency plan of moving to virtual outlined where possible. Observation data collection in WP3 has been kept to a minimum to balance rigour with burden on staff.

Trust stakeholders are difficult to engage due to competing priorities	Fatigue as a priority area has come from within the sector, aided and informed by our prior research and evidence from industry partners. We have successfully interviewed senior Trust leadership and front-line staff across all NHS English Ambulance Trusts during a pandemic (HEE-funded SWAP study IRAS ID 261350), reflecting our experience in engaging key stakeholders in workplace health research and agility in responding to unforeseen challenges.
Key personnel change or leave roles	Each WP has three named Leads, we have engaged the support and participation of key organisations and will work with these organisations to replace any personnel who move on from the project. In WP4 Ambulance Q will support existing and new fatigue action groups which will ensure no single person is responsible for feasibility testing or sustainability.
Adverse media from highlighting potentially unsafe working conditions and risk to patient safety	A Communication Strategy (Appendix) has been developed to manage communication with the ambulance sector about the project purpose, progress and findings. We have used this approach successfully in previous research studies of workplace health which can illuminate concerns of interest to the public.

Health Research Authority (HRA) and Research Ethics Committee approvals

The study will adhere to the UK Framework for Health and Social Care research and appropriate HRA and ethics approval will be obtained. Amendments will be submitted as required. Approvals will include a Data Management plan, data sharing agreement, and Communications Strategy (Appendix) as part of risk mitigation.

The Chief Investigator or designee will ensure that capacity and capability confirmation from participating NHS organisations are in place following the HRA approval of the study. For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the HRA for them to issue approval for the amendment. The Chief Investigator or designee will work with sites so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

Patient and public involvement

Mr Dearling is PPI Lead and Co-Applicant for this proposal. As PPI Co-Applicants Dearling and Co-Applicant Rogers will be members of the Project Management Group, and all three PPI representatives will be members of the Study Advisory Group. PPI representatives will be full members of the team, contributing to the theory of change and logic model development particularly around selection of patient-preferred outcomes and pathways to patient benefit, data analysis and interpretation, preparation of the NIHR report, and scientific outputs including publications and presentations. Rogers is new to his PPI role. He will be fully supported in this role by Mr Dearling and the NHS Norfolk & Waveney CCG-supported Norfolk Public & Patient Involvement in Research group (PPIRes). All PPI team members will also have access to the expertise of the NIHR ARC East of England Public and Community Involvement, Engagement and Participation Group who will provide opportunities for support, networking and advice on public impact activities. Mr Dearling and Mr Rogers will guide the public dissemination output, and have input to the briefing materials prepared for staff and managers in Trusts and HEIs who teach paramedic sciences.

Specific areas of contribution include:

Work Package 1: PPI members will attend the co-design event to ensure the patient and public perspective is considered in the FRMS design workshops. They will review the first version of the resultant FRMS.
Work Package 2: The topic guide will be reviewed by Dearling and Rogers to incorporate their views on the patient and system performance outcome indicators we should ask about.

Protocol compliance

Any protocol deviations or breaches will be notified to the Chief Investigator, who will follow Sponsor protocols. The SSC will be advised.

Data protection and confidentiality

All data management will be in accordance with requirements of the General Data Protection Regulation (2018) and Data Protection Act 1998. This includes any collection, storage, processing and disclosure of personal information.

External processing and hosting of data

MURAL Team+ (WP1): MURAL Team+ is subscription-based, with ISO 9001 certifications and complies with GDPR, and uses cloud-based data storage via Microsoft Azure in compliance with the EU-US Privacy Shield Principles. It has rigorous security protocols: data only resides in the production environment encrypted with AES-256; all network communication uses TLS v1.2, and it is encrypted and authenticated using AES_128_GCM and uses ECDHE_RSA as the key exchange mechanism. UEA and HSC hold licenses. HSE's information sits on a secured server that has to meet the requirements of the UK government Security Policy Framework.

Jisc Online Surveys (WP1, WP4): Jisc are a not-for-profit organisation for digital services and infrastructure, operated and owned by HEIs and further education institutions on a membership basis. Online Surveys was developed by Jisc specifically for education and research institutions. Online Surveys are GDPR compliant, with data stored by Amazon Web Services (AWS) in the Republic of Ireland certified to ISO 27001. All systems are physically located within datacentres operated by AWS. All survey responses are collected over encrypted SSL (TLS) connections, The Online Surveys licensee acts as the Data Controller. Jisc acts as the Data Processor, only processing the licensee's survey data in accordance with their instructions.

Transcript Divas (Limited) (WP2, WP3) is a London based, United Kingdom registered transcription company operating since 2013 (UK company number: 08785529). Transcript Divas are officially registered Data Controllers, and are registered on the UK Government Data Protection Public Register. Recordings and completed transcripts are received through an encrypted server (not email). Secure protocols for communication and transferring data such as encrypting data in transit e.g. HTTPS and encrypting data when it is at rest/stored e.g. AES256, are used. Transcripts and transcript recordings are hosted on Transcript Divas (Limited) London based server. Recordings and transcripts will be deleted from the servers within 60 days of completion. Transcript Divas (Limited) use host-based firewalls on both computers and mobile phones and where possible, wi-fi routers. Systems are password-protected, and when possible, use 2-factor authentication. Transcript Divas (Limited) will complete a Transcription Confidentiality Agreement.

Data storage and archiving

All information provided during the study will be stored in accordance with the Data Protection Act 2018 and the General Data Protection Regulation (GDPR). Names and email

addresses, and consent forms with identifiable data, will be stored in separate respective OneDrive folders on UEA (sponsor) servers. Names and email addresses will be destroyed once the study is complete and results sent to participants. At the end of the research period research data (anonymised/pseudonymised) and encrypted consent information will be passed into central file storage within the Faculty of Medical and Health Sciences (UEA, Sponsor) and destroyed after 10 years. As per UEA policy all information processed and collected as part of this research is considered privileged information.

Virtual workshop materials (WP1)

The virtual workshops will be hosted on the HSE and UEA Microsoft Teams platforms and using the MURAL virtual whiteboard programme. MS Teams and MURAL material will be downloaded to UEA servers. Data generated during the workshop consists of online written material such as notes, comments and anything recorded in the chat function. Notes and annotations on the MURAL whiteboard can be made anonymously. Any identifying material (such as in chat) will be deidentified prior to analysis and codes assigned to individuals. The workshop will not be audio recorded to encourage free discussion.

Online surveys (WP1, WP4)

Online surveys will be administered using the Jisc Online Surveys platform as described above. Survey data will be downloaded to secure UEA servers and only accessed by the UEA research team, who will conduct the analysis.

Interviews and observations with staff and patients (WP2, WP3)

Participants will be de-identified and will be given a participant identification number. Data will be de-identified, and if quotations of free text or interview responses are used within reports, these will be given a pseudonym. Only de-identified responses will be shared within the research team in the analysis process. Interviews will be digitally recorded and transcribed (Transcript Divas) and stored on password protected University of East Anglia OneDrive. All data will be de-identified and recordings deleted after transcription.

Data sharing between organisations

Data sharing with NHS organisations will be detailed and agreed via an Organisation Information Document.

Indemnity

For harm to participants arising from management and design of the research, provided by UEA as the Sponsor. For harm to participants arising from conduct of research, provided by NHS as participants recruited from NHS sites only.

9. DISSEMINATION POLICY

The dissemination activities and anticipated impact are presented in Table 2. The Work Packages have been designed to produce some rapid outputs as the research proceeds. The full list of impact activities is shown in Table 2 for context. With all outputs co-produced with research end-users, our focus on linking to patient and system outcomes, and producing tailorable implementation guidance, our approach will help maximise sustainable uptake and longer-term impact on patient- and system-prioritised outcomes. Key parties have been integral to the design and development of this work program, and are involved throughout. Many of these key parties will act as project and dissemination champions.

Outputs are summarised against each WP above and detailed in Table 2 below, and include:

- A co-produced comprehensive FRMS for the NHS ambulance sector
- Implementation guidance that allows tailoring to the health, operational, and implementation-readiness of each Trust, taking into account existing/planned activities
- Journal outputs
- Briefing note for NHS Ambulance Trust senior leaders with presentations delivered to key networks as we did in formulating this proposal (AACE National Council of CEOs and Board Chairs, HR (People & Culture) Directors Group, Operations Group, Directors of Quality, Governance and Risk Group, Wellbeing Leads Group)
- Webinars for NHS audiences on fatigue management and promoting sleep health including learning from pandemic impacts
- Guidance for HEIs on curricula on sleep health and managing fatigue at work for paramedic science students and other non-medical health profession students
- Case studies for NHS Employers under the "Retention and Staff Experience" theme which includes *Health and Wellbeing*, *Ambulance Staff* and *Flexible Working* (see https://www.nhsemployers.org/case-studies-and-resources for format)
- Short "talking head" and animation videos for social media developed with our patient and staff representatives.

Table 2. Outputs, how these will enter the system via specified target audience, and anticipated impact.

Impact output/activity	**Target audience**	**Anticipated impact**
Promotion of best practice FRMS (WP1) via masterclass webinars led by HSE with AACE and Ambulance Q	Separate webinars for senior leaders/managers and staff	Increased awareness of evidence-based strategies for sleep health and fatigue mitigation, and engagement with subsequent WPs across the sector
NHS Employers case study: co-producing a fatigue management strategy that links staff wellbeing to operations (WP1)	Senior leaders in NHS Ambulance Trusts and other non-hospital NHS settings, wellbeing leads, operations leads	Insights on barriers and facilitators to co-producing a complex workforce intervention that spans operations, governance, HR, and staff wellbeing, highlighting use of NPT constructs for intervention design
Briefing note with presentations: high-level summary of study findings focusing on operational implications and opportunities for improving safety (WP1,2 and WP3,4)	AACE Council (CEOs & Chair Boards), directors Groups: HR, Operations, Quality and Risk	Increased awareness of link between staff fatigue and safety, how to implements preferred strategies which may include smart rostering, napping on shift, fatigue identification tools, and importance of promoting sleep health as a risk mitigation strategy
Webinar on sleep health	All ambulance staff with specific recommendations for staff who work nights	Increased awareness of self-directed and formal strategies that may help, may eventually lead to higher uptake of support leading to improved sleep quality and less fatigue at work
NHS Employers case study: sleep health promotion	HR and Wellbeing teams in NHS Trusts and social care across all health sectors	Insights on barriers/facilitators to sleep innovations in NHS and social care workforces, highlight use of NPT constructs for system design
Briefing note outlining recommendations for College of Paramedics curricula guidance for HEIs	HEI curriculum developers	Options for curricula revisions to better prepare newly qualified paramedics for shift work and disrupted sleep. May

		ultimately lead to better staff experience, retention and wellbeing
Media promotion, format advised by patient and staff PPI input e.g. short social media videos/animations	Patients, shift workers in other safety-critical sectors, general public	Increased public engagement with NHS research on staff health and wellbeing, and its importance for understanding how to improve patient experience
Workshop on implementation guidance (WP4) with Ambulance Q	Ambulance sector via the Ambulance Leadership Forum (AACE annual conference)	This annual meeting of the UK ambulance sector coincides with the conclusion of the project and provides a final opportunity to disseminate the project in its entirety and provide an in-person opportunity to work through implementation guidance

Anticipated impact: Our theory of change and logic model will detail the pathway to impact for short, medium, and longer-term outcomes. All stakeholder groups have contributed to this proposal and/or been involved in an advisory role, and will help tailor dissemination to their respective end-users.

Ambulance sector: Short-term impacts include access to practical guidance for staff, managers, and senior leaders to reform their fatigue and sleep health practices. Fatigue and poor sleep were recognised staff issues before COVID-19, and have been made even more prominent as staff have dealt with the pandemic and will continue to deal with sector disruptions and their own health impacts (e.g. fatigue from long COVID). The detailed FRMS implementation guidance will help Trusts allocate resources to actions that are likely to have the most impact on patient and staff outcomes, including, over time, contributing to a reduced risk of near-misses and safety incidents. As an example of our hypothesised pathway to patient benefit we will be developing through the logic model, interventions to reduce circadian disruption such as bright light therapy or personalised rotas could result in: improved sleep quality → improved alertness on shift → improved clinical decision making and communication with patients → improved patient experience → safer care. Better support for sleep and proactive identification and management of fatigue on shift will make a significant contribution to shift workers' quality of life and quality of work. Co-producing these solutions with staff has the potential to increase staff engagement and reduce absence. An improved safety culture may save the NHS money over the longer-term through helping prevent costly staff and patient safety incidents. This sector-wide project, if successful, has the longer-term potential to improve the experience of very large numbers of people who use ambulance services in every NHS Ambulance Trust in the UK.

Other sectors of the NHS and social care: No sector of the NHS or social care has yet developed and implemented a comprehensive FRMS. NHSE/I has invested some resources into selected fatigue mitigation strategies (e.g. napping facilities) but this has to date been restricted to acute hospitals. If successful this project will provide a roadmap for how an FRMS can be developed and implemented in other sectors, particularly those that have had little current activity in fatigue management such as community services, mental health services or social care, all of whom have 24-hour operations.

General public and other shift-workers: From our dissemination activities patients and the general public will have a greater understanding of the fatigue pressures affecting ambulance staff and the need for accommodations on shift like meal breaks and short naps. Our findings on how to implement sleep interventions will be potentially of interest to shift-workers in other industries.

REFERENCES

1. McDowall K, Murphy E, Anderson K. The impact of shift work on sleep quality among nurses. Occup Med. 2017;67(8):621-5.
2. Geiger-Brown J, Rogers VE, Trinkoff AM, Kane RL, Bausell RB, Scharf SM. Sleep, sleepiness, fatigue, and performance of 12-Hour-shift nurses. Chronobiology International. 2012;29(2):211-9.
3. Patterson PD, Weaver MD, Frank RC, Warner CW, Martin-Gill C, Guyette FX, et al. Association between poor sleep, fatigue, and safety outcomes in emergency medical services providers. Prehospital Emergency Care. 2012;16(1):86-97.
4. Donnelly EA, Bradford P, Davis M, Hedges C, Socha D, Morassutti P. Fatigue and safety in paramedicine. CJEM. 2019:1-4.
5. McClelland L, Plunkett E, McCrossan R, Ferguson K, Fraser J, Gildersleve C, et al. A national survey of out-of-hours working and fatigue in consultants in anaesthesia and paediatric intensive care in the UK and Ireland. Anaesthesia. 2019:10.1111/anae.14819.
6. Beillon LM, Suserud BO, Karlberg I, Herlitz J. Does ambulance use differ between geographic areas? A survey of ambulance use in sparsely and densely populated areas. Am J Emerg Med. 2009;27(2):202-11.
7. McGuffie AC, Graham CA, Beard D, Henry JM, Fitzpatrick MO, Wilkie SC, et al. Scottish urban versus rural trauma outcome study. The Journal of Trauma. 2005;59:632-8.
8. Sanderson K, Clark LV, Lazar AS, Khadjesari Z, Hall H, Foster T, et al. SleepSmart: confidential internal research report for EEAST Board. UK: University of East Anglia; 2020.
9. Pritchard G, Phung V-H, Bell F, Siriwardena N, Wankhade P, Kelly H, et al. Policy and practice for staff wellbeing in NHS Ambulance Trusts: a content analysis. SWAP Study. Interim Report to Health Education England. UK: University of East Anglia; 2020.
10. Health and Safety Executive. Managing Shift Work. Health and safety guidance (HSG 256) . 2006. Report No.: ISBN 0-7176-6197-0.
11. Noone P, Waclawski E. Fatigue risk management systems needed in healthcare. Occup Med. 2018;68(8):496-8.
12. International Civil Aviation Organisation. Fatigue Management Guide for Airline Operators 2nd Edition (replacing Fatigue Risk Management Systems: Implementation Guide for Operators). Montreal,: IATA,; 2015.
13. Farquhar M. Are aviation industry fatigue risk management strategies needed in healthcare? Anaesthesia. 2017:72:1419-20.
14. Johnson M, Hara RO, Hirst E, Weyman A, Turner J, Mason S, et al. Multiple triangulation and collaborative research using qualitative methods to explore decision making in pre-hospital emergency care. BMC Medical Research Methodology. 2017;17:1-11.
15. Care Quality Commission. Opening the door to change: NHS safety culture and the need for transformation. UK: CQC; 2018.
16. Turner J, Siriwardena AN, Coster J, Jacques R, Irving A, Crum A, et al. Developing new ways of measuring the quality and impact of ambulance service care: the PhOEBE mixed-methods research programme. NIHR Journals Library: 2019;7:3.
17. Lerman SE, Eskin E, Flower DJ, George EC, Gerson B, Hartenbaum N, et al. Fatigue risk management in the workplace. 2012;54(2):231-58.
18. National Health Service. We are the NHS: People Plan 2020/21 - action for us all. UK: NHS,; 2020.
19. Clark LV, Fida R, Skinner J, Murdoch J, Rees N, Williams J, et al. Mental health, well-being and support interventions for UK ambulance services staff: an evidence map 2000 to 2020. British Paramedic Journal. 2021; 5:25-39.
20. Patterson PD, Higgins JS, Van Dongen HPA, Buysse DJ, Thackery RW, Kupas DF, et al. Evidence-based guidelines for fatigue risk management in emergency medical services. Prehospital Emergency Care. 2018;22(sup1):89-101.
21. Barger LK, Runyon MS, Renn ML, Moore CG, Weiss PM, Condle JP, et al. Effect of Fatigue Training on Safety, Fatigue, and Sleep in Emergency Medical Services Personnel and Other Shift Workers: A Systematic Review and Meta-Analysis. Prehospital Emergency Care. 2018;22(sup1):58-68.

22. Patterson PD, Runyon MS, Higgins JS, Weaver MD, Teasley EM, Kroemer AJ, et al. Shorter Versus Longer Shift Durations to Mitigate Fatigue and Fatigue-Related Risks in Emergency Medical Services Personnel and Related Shift Workers: A Systematic Review. Prehospital Emergency Care. 2018;22(sup1):28-36.
23. Temple JL, Hostler D, Martin-Gill C, Moore CG, Weiss PM, Sequeira DJ, et al. Systematic Review and Meta-analysis of the Effects of Caffeine in Fatigued Shift Workers: Implications for Emergency Medical Services Personnel. Prehospital Emergency Care: 2018;22(sup1):37-46.
24. Martin-Gill C, Barger LK, Moore CG, Higgins JS, Teasley EM, Weiss PM, et al. Effects of Napping During Shift Work on Sleepiness and Performance in Emergency Medical Services Personnel and Similar Shift Workers: A Systematic Review and Meta-Analysis. Prehospital Emergency Care. 2018;22(sup1):47-57.
25. James FO, Waggoner LB, Weiss PM, Patterson PD, Higgins JS, Lang ES, et al. Does Implementation of Biomathematical Models Mitigate Fatigue and Fatigue-related Risks in Emergency Medical Services Operations? A Systematic Review. Prehospital Emergency Care. 2018;22(sup1):69-80.
26. Querstret D, O'Brien K, Skene DJ, Maben J. Improving fatigue risk management in healthcare: A systematic scoping review of sleep-related/fatigue-management interventions for nurses and midwives. International Journal of Nursing Studies. 2020;106:103513.
27. Redeker N, Caruso C, Hashmi S, Mullington J, Grandner M, Morgenthaler T. Workplace Interventions to Promote Sleep Health and an Alert, Healthy Workforce. Journal of Clinical Sleep Medicine. 2019;15:649-57.
28. Slanger TE, Gross JV, Pinger A, Morfeld P, Bellinger M, Duhme AL, et al. Person-directed, non-pharmacological interventions for sleepiness at work and sleep disturbances caused by shift work. Cochrane Database of Systematic Reviews. 2016(8).
29. O'Cathain A, Croot L, Duncan E, Rousseau N, Sworn K, Turner KM, et al. Guidance on how to develop complex interventions to improve health and healthcare. BMJ Open. 2019;9(8):e029954.
30. May CR, Cummings A, Girling M, Bracher M, Mair FS, May CM, et al. Using Normalization Process Theory in feasibility studies and process evaluations of complex healthcare interventions: a systematic review. Implementation Science. 2018;13:80.
31. Finch TL, Girling M, May CR, Mair FS, Murray E, Treweek S, et al. Improving the normalization of complex interventions: part 2 - validation of the NoMAD instrument for assessing implementation work based on normalization process theory. BMC Med Res Meth. 2018;18:135.
32. Murray E, Treweek S, Pope C, MacFarlane A, Ballini L, Dowrick C, et al. Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. BMC Medicine. 2010;8:63.
33. McNaughton RJ, Steven A, Shucksmith J. Using Normalization Process Theory as a Practical Tool Across the Life Course of a Qualitative Research Project. Qualitative Health Research. 2020;30:217-27.
34. Diamond IR, Granta RC, Feldman BM, Pencharzd PB, Lingd SC, Moorea AM, et al. Defining consensus: A systematic review recommends methodologic criteria for reporting of Delphi studies. Journal of Clinical Epidemiology. 2014;67:401-9.
35. Banno M, Tsujimoto Y, Kataoka Y. Reporting quality of the Delphi technique in reporting guidelines: a protocol for a systematic analysis of the EQUATOR Network Library. BMJ Open. 2019;9:e024942.
36. Vetter C, Fischer D, Matera JL, Roenneberg T. Aligning work and circadian time in shift workers improves sleep and reduces circadian disruption. Current Biology. 2015;25:907-11.
37. Lovato N, Lack L. Circadian phase delay using the newly developed re-timer portable light device. Sleep and Biological Rhythms. 2016;14(2):157-64.
38. Basner M, Dinges DF. Maximizing sensitivity of the psychomotor vigilance test (PVT) to sleep loss. Sleep. 2011;34(5):581-91.
39. Butler C, Bell J. [Commercial in Confidence]. UK: Health and Safety Executive; 2017.

40. Butler C, Bell J. [Commercial in Confidence]. UK: Health and Safety Executive; 2014.
41. Jose K, Venn A, Jarman L, Seal J, Teale B, Scott J, et al. Partnering Healthy@Work: an Australian university—government partnership facilitating policy-relevant research. Health Promotion International. 2017;32:964–76.
42. Shann C, Martin A, Sanderson K, Warnecke E, Dawins S, Bartlett L, et al. An integrated approach to workplace mental health: nine priorities for implementation in Australia. Tasmania: University of Tasmania; 2017.
43. De Silva MJ, Breuer E, Lee L, Asher L, Chowdhary N, Lund C, et al. Theory of Change: a theory-driven approach to enhance the Medical Research Council's framework for complex interventions. Trials. 2014;15:267.
44. Rolfe U, Pope C, Crouch R. Paramedic performance when managing patients experiencing mental health issues – Exploring paramedics' Presentation of Self. International Emergency Nursing. 2020;49:100828.
45. Palinkas LA, Horwitz SM, Green CA. Purposeful sampling for qualitative data collection and analysis in mixed method implementation research. Adm Policy Ment Health. 2015;42:533-44.
46. McCann L, Granter E, Hyde P, Hassard J. Still blue-collar after all these years? An ethnography of the professionalization of emergency ambulance work. Journal of Management Studies. 2013;50:750-6.
47. Agreli H, Barry F, Burton A, Creedon S, Drennan J, Gould D, et al. Ethnographic study using Normalization Process Theory to understand the implementation process of infection prevention and control guidelines in Ireland. BMJ Open. 2019;9:e029514.
48. Booker MJ, Purdy S, Barnes R, Shaw ARG. Ambulance use for 'primary care' problems: an ethnographic study of seeking and providing help in a UK ambulance service. BMJ Open. 2019;9(10):e033037.
49. Oswald Handling the Hawthorne effect: the challenges surrounding a participant observer. Review of Social Studies. 2014;1:53-73.
50. O'Cathain A, Knowles E, Bishop-Edwards L, Coster J, Crum A, Jacques R, et al. Understanding variation in ambulance service non-conveyance rates: a mixed methods study. Health Serv Deliv Res 2018;6(19).
51. Memish K, Martin A, Bartlett L, Dawkins S, Sanderson K. Workplace mental health: An international review of guidelines. Preventive Medicine. 2017;101:213-22.
52. Gabbay J, le May A. Mindlines: making sense of evidence in practice. British Journal of General Practice. 2016;66:402-3.
53. Pinnock H, Barwick M, Carpenter CR, Eldridge S, Grandes G, Griffiths CJ, et al. Standards for Reporting Implementation Studies (StaRI) Statement. BMJ Clinical Research Ed. 2017;356:i6795-i.
54. Keenan J, Poland F, Boote J, Howe A, Wythe H, Varley A, et al. "We're passengers sailing in the same ship, but we have our own berths to sleep in': Evaluating patient and public involvement within a regional research programme: An action research project informed by Normalisation Process Theory. Plos One. 2019;14:e0215953.