Care Under Pressure 3 HRA Protocol

FULL/LONG TITLE OF THE STUDY

Care Under Pressure 3: Optimising the delivery and impacts of interventions to reduce hospital doctors' mental ill-health in the NHS

SHORT STUDY TITLE / ACRONYM

CUP3

PROTOCOL VERSION NUMBER AND DATE

Protocol Version: 1.1

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HRA Protocol Compliance Declaration

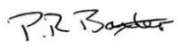
This protocol has regard for the HRA guidance and order of content.

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:	
Signature: 	Date: 31/10/22
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Name: (please print): Daniele Carrieri	

LIST OF CONTENTS

KEY STUDY CONTACTS

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Sponsor	University of Exeter Ms Pam Baxter – Research Governance Manager (Health and Social Care)
Research partners/collaborators	University of Oxford Hull York Medical School Devon Partnership NHS Trust
Funder(s)	NIHR HS&DR Award ID: NIHR132931 https://fundingawards.nihr.ac.uk/award/NIHR132931
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Committees	Steering group Project advisory group NHS Trust local stakeholder groups (at each study site)

STUDY SUMMARY

Study Title	Care Under Pressure 3: Optimising the delivery and impacts of interventions to reduce hospital doctors' mental ill-health in the NHS
Internal ref. no. (or short title)	CUP3
Study Design	Qualitative; Realist evaluation
Study Participants	NHS Trust doctors and those involved in supporting them in their Trusts, e.g. service managers, occupational health
Planned Size of Sample	160
Follow up duration (if applicable)	N/A
Planned Study Period	February 2023 to February 2024 (data collection) The project end date is June 2024. By this date all data will have been collected and analysed, the various project governance groups will have met for the last time, and a final report will have been submitted to the funder. Academic presentations and publications will come out after this date and the impact work would be ongoing beyond June 2024.
Research Aim	Our aim is to work with and learn from eight purposively selected NHS Trusts, building on the principles developed in Care Under Pressure 1 (CUP1), to develop an implementation toolkit for all NHS Trusts to optimise their strategies to reduce doctors' mental ill-health and its impacts on the workforce and patient care.

FUNDING AND SUPPORT IN KIND

Funder(s)	**Financial and non-financial support given**
NIHR HD&SR	£582,985.42 https://fundingawards.nihr.ac.uk/award/NIHR132931

ROLE OF STUDY SPONSOR AND FUNDER

The Sponsor (University of Exeter) assumes overall responsibility for the initiation and management of the study described here.

The funder (NIHR) has commissioned this research. The study design has been developed by the research team in consultation with representatives of the funder. The funder will have no role in the conduct of the research, data analysis and interpretation, or writing of the final study report.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS AND INDIVIDUALS

The CUP3 project will involve three groups: a steering group; a project advisory group; and NHS Trust local stakeholder groups (at each study site). The core research team will work with these groups throughout the course of the research, and their input will feed into the research, project outputs and dissemination through the core project team (Figure 1).

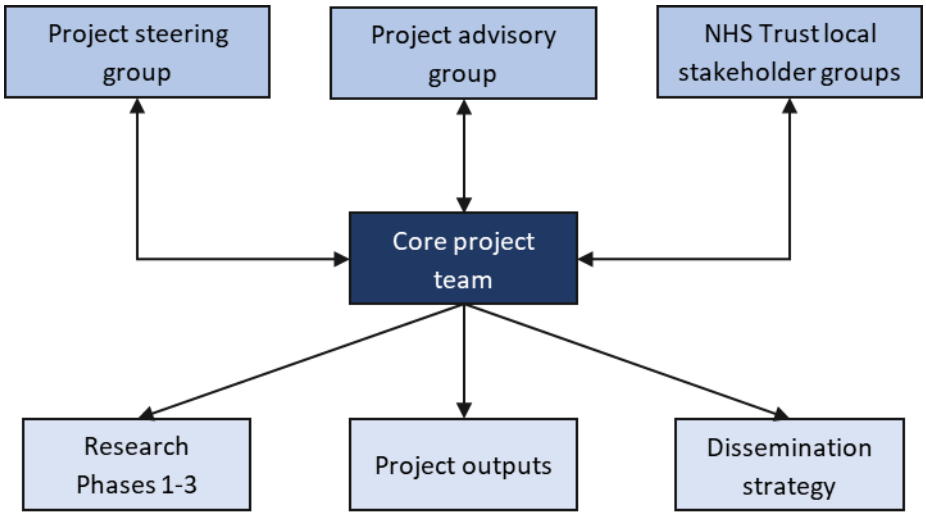

Figure 1. Relationships between the core project team and three groups.

Project Steering Group

The steering group will comprise a small group of individuals with close interests in the topic area and relevant methodological expertise, representing both university and NHS settings. The steering group will monitor progress against milestones and spend against budget, provide advice where necessary, promote the project, and facilitate communication. Professor Jill Maben (Professor of Health Services Research and Nursing, University of Surrey) will chair the group.

Project Advisory Group

CUP3 will be supported by our project advisory group, originally established for the Care Under Pressure 1 (CUP1) project. We will review and extend the membership, as needed, during the project as we did during CUP1. The group will meet regularly throughout the CUP3 project to discuss the research process, findings, outputs, and dissemination. The membership represents individuals from different perspectives, including doctors from shortage specialties, doctors who have experienced mental ill-health, other healthcare professionals, NHS managers, patients and the public, researchers, charities with an interest in mental ill-health, and doctor support organisations such as the Practitioner Health Programme (PHP).

Although not conventionally seen as members of the public or patients in health research, doctors are important stakeholders in CUP3 since they are the direct target of interventions and initiatives to prevent and address doctors' mental ill-health in NHS Trusts. Moreover, when they use mental health services, they can become patients. This is why the CUP3 project advisory group includes doctors from different specialties and at different career stages (both those with direct experience of mental ill-health and those who have an interest in the area).

Given the potential tensions and inhibitions that may exist for some group members within a large meeting format, we will also provide opportunities to discuss the topic further with the research team between meetings. We recognise that not every member will be able to attend every meeting and will encourage non-attenders to send a nominee and/or to contribute their insights by another means, e.g. email and/or telephone conversation.

NHS Trust local stakeholder groups

We will work with site leads at each of the recruited NHS Trusts to facilitate recruitment and engagement of local stakeholders (e.g. doctors, service managers, and patients) during the project.

PROTOCOL CONTRIBUTORS

- The protocol has been developed by the Co-Chief Investigators Dr Daniele Carrieri and Professor Karen Mattick, with input from the co-investigators: Dr Jason Hancock; Dr Geoff Wong; Dr Chrysanthi Papoutsi; Dr Mark Pearson; and the wider research team: Dr Alison Pearson; Dr Charlotte Bramwell; Dr Anna Melvin; and Dr Jessica Scott.
- The NIHR grant application, including the protocol, was reviewed by the South West Research Design Services (RDS), including their patient and public involvement (PPI) representatives and advisors.

- The Sponsor has no input into study design, conduct, data analysis, interpretation, manuscript writing, or dissemination of findings.
- The funder has been consulted on the study design for this research. The funder has no input into data analysis or interpretation, or the writing of the final study report.
- Neither the Sponsor nor the funder control the final decisions regarding any aspects of the study.

KEY WORDS

Doctors

Well-being

Mental health

Support

STUDY FLOW CHART

Flow charts are shown for the overall project (

Figure 2) and participant involvement (Figure 3).

Phase 1 [Months 1-4]	
Objective 1: Develop a typology of interventions to reduce doctors' mental ill-health and use this to inform sampling of eight NHS Trusts	**Methodology:** Analyse interventions in CUP1 review, and other relevant sources – drawing on CUP1 principles and engagement with project advisory group
Outputs	
• Typology of interventions; initial version of CUP3 Programme Theory • A purposive sampling strategy for Trust recruitment in Phase 2	

Phase 2 [Months 5-20]	
Objective 2: Work with eight recruited Trusts to develop an explanatory account of whether and how their interventions are working, for whom, under what circumstances and why (not)	**Methodology**: Realist evaluation of Trusts' interventions: individual/group interviews with relevant staff (e.g. doctors, NHS managers); and where possible workplace observations, and analysis of relevant documents to contextualise findings
Outputs	
• Final CUP3 Programme Theory • Evidence-based and tailored guidance for each participating NHS Trust on how they can improve their implementation of interventions to reduce doctors' mental ill-health	

Phase 3 [Months 21-24]	
Objective 3: Develop an evidence-based toolkit for all NHS Trusts at national level to evaluate and optimise their strategies to reduce doctors' mental ill-health	**Methodology:** Engage with project advisory group (and optional involvement of recruited NHS trusts) to develop a toolkit
Outputs	
• An evidence-based implementation toolkit to help all NHS Trusts nationally to evaluate and optimise their strategies to reduce doctors' mental ill-health • An outputs dissemination strategy	

Overall Research Outputs
1. An evidence-based implementation toolkit to help all NHS Trusts nationally to evaluate and optimise their strategies to reduce doctors' mental ill-health 2. Tailored and actionable guidance to improve the delivery of interventions to reduce doctors' mental ill-health in the eight recruited NHS Trusts 3. Creative outputs to help disseminate and use the toolkit (e.g. animations, cartoons) 4. At least two manuscripts for publication in a high-impact peer-reviewed journal (e.g. BMJ, JAMA, or Journal of Health Services Research & Policy) 5. NIHR interim and final report

Figure 2. Overview of the project.

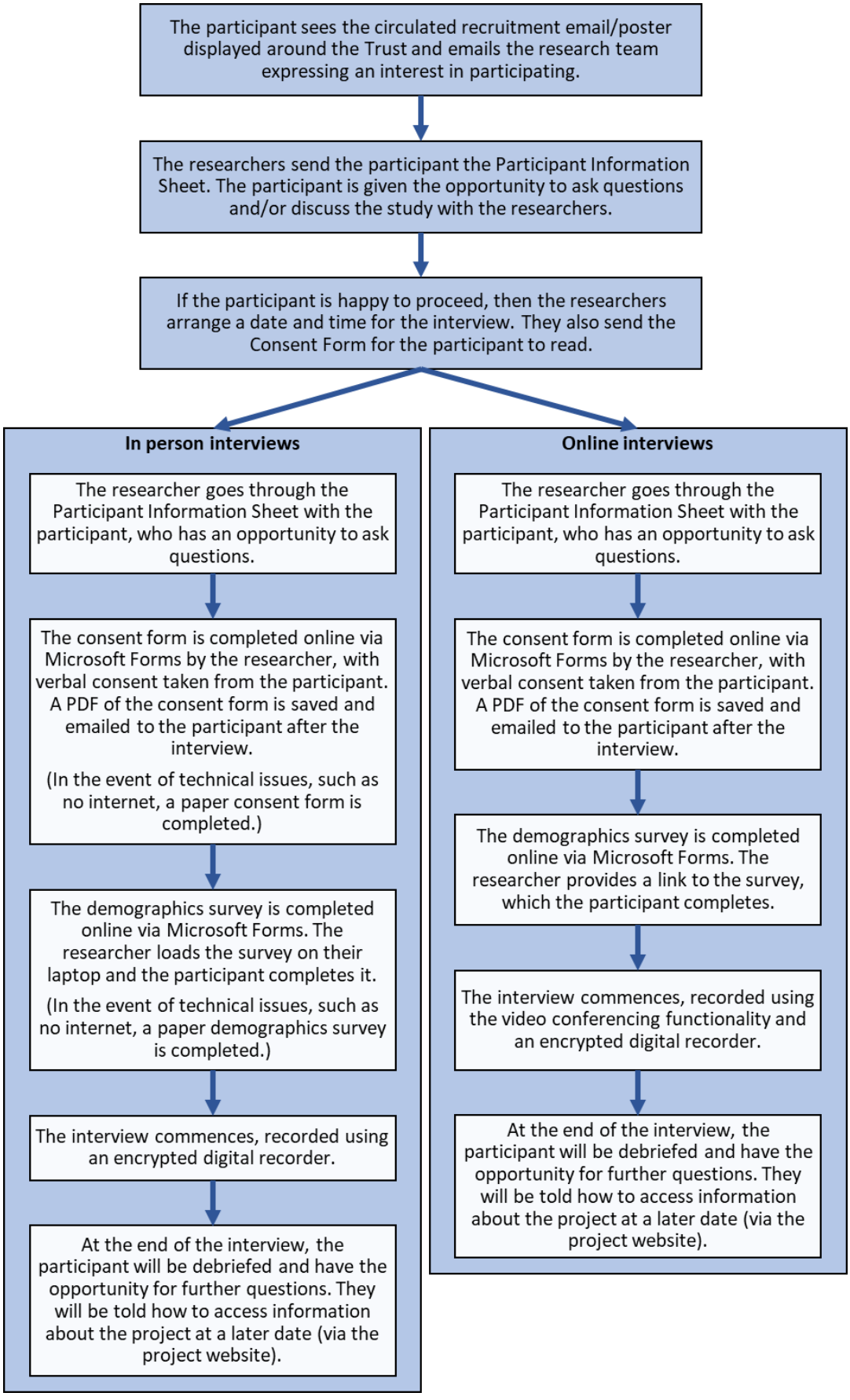

Figure 3. Data collection process for the interviews in Phase 2.

STUDY PROTOCOL

Care Under Pressure 3: Optimising the delivery and impacts of interventions to reduce hospital doctors' mental ill-health in the NHS

1. BACKGROUND

The NHS needs motivated, compassionate, well-supported doctors to provide the best care for patients. However, doctors experience high levels of stress, anxiety, and other mental illnesses due to challenging demands and pressurised work environments. They worry about patient safety, the consequences of letting patients and colleagues down, and their professional reputation. Many work while unwell or choose to leave the profession or the NHS, leading to shortages of doctors. Existing workplace support for doctors seems to be having limited effect and often does not take into account the different factors contributing to mental ill-health in doctors (e.g. individual, professional, organisational, social factors), nor whether interventions have been implemented effectively. This work seeks to address these gaps, building on our previous realist review Care Under Pressure 1 (CUP1), which synthesised evidence to produce key principles and recommendations to reduce doctors' mental ill-health in the workplace, and its impact on patient care.

1.1. The problem: mental ill-health in doctors

The growing incidence of mental ill-health in doctors has been a major issue in the UK and elsewhere, even prior to the COVID-19 pandemic (Berwick, 2020; Søvold et al., 2021; The Lancet, 2019a). This problem has significant and far-reaching implications, including: poor quality or inconsistent patient care; absenteeism; presenteeism; workforce attrition and retention; and substance addiction (Bodenheimer and Sinsky, 2014; Elton, 2019). One of the main objectives of the 2020/21 NHS People Plan is "to keep our people safe, healthy and well – both physically and psychologically" (NHS England, 2020, p. 6). Yet, in the NHS staff survey conducted during October and November 2020, around 44% of staff (and 40% of doctors) indicated they had been unwell as a result of work-related stress in the previous year (O'Dowd, 2021), increasing from previous years (Thornton, 2019). Additionally, nearly half of those surveyed said they had gone to work in the last three months when not feeling well enough to perform their duties, around a third of staff said that they were considering quitting their job, and a fifth indicated that they may leave the health service completely (O'Dowd, 2021). With the COVID-19 pandemic, the need to address mental ill-health in doctors is even more crucial to the future of the NHS (Billings et al., 2021; Unadkat and Farquhar, 2020).

NHS staff mental health is a complex problem and is prevalent among all groups of healthcare professionals. While it is tempting to address as much of this problem as possible in one study, we

propose to tackle one staff group initially: hospital doctors and doctors-in-training, across specialties and career stages. The focus on hospital doctors reflects: the fact that NHS Trusts (i.e. secondary care) are the largest employers of doctors; the significant potential for unwell doctors to cause harm to patients; and the financial implications of doctors' mental ill-health (Wilkinson, 2015). Similar studies are needed in primary care settings but, given the significant structural and organisational diversity between primary and secondary care, this is beyond the scope of the current project. Focusing on one staff group in one setting allows us to conduct in-depth research into the specific sociological, structural and organisational elements that we know to be important and ensures we can be confident of the findings for hospital doctors. These findings may prove to be transferable to other groups to a greater or lesser extent, when explored through future research.

1.2. Review of the evidence

The urgency and salience of the problem of mental ill-health in doctors, even before COVID-19, is reflected in the growing number of systematic reviews and primary research studies (Panagioti et al., 2017), opinion pieces (The Lancet, 2019b), recommendations (Health Education England, 2019), and doctors' memoirs (Gask, 2019). Feelings of isolation and lack of job control have been identified as major causes of mental ill-health in doctors, both in the CUP1 realist review (Carrieri et al., 2020a) and other systematic reviews (Panagioti et al., 2017). Evidence suggests that both individual doctors and organisations have a role to play to address the issue of mental ill-health (Rothenberger, 2017). The GMC doctors' well-being report (West and Coia, 2019) recommended that workplaces should meet the "ABC of doctors' core needs": Autonomy (having control over work), Belonging (feeling connected to teams and valued), and Competence (delivering valued outcomes). However, mental ill-health in doctors is unlikely to improve unless two important gaps are addressed.

The first gap is that most research is undertaken within disciplinary silos and does not consider simultaneously the many dimensions (e.g. individual, organisational, professional, social factors) that may negatively affect doctors' well-being (Wilkinson, 2015). The current emphasis on resilience (and in the COVID-19 period on heroism (Cox, 2020)) places responsibility for well-being with the individual, but resilience training alone is unlikely to solve such a complex and multidimensional issue, and may even aggravate how doctors experience work-related pressures (Carrieri et al., 2019; Cheshire et al., 2017; LaDonna et al., 2022; Panagioti et al., 2017).

The second gap is a lack of guidance on how to implement existing recommendations in organisational settings to ensure they work in the ways intended, i.e. how to put theory into practice (Carrieri et al., 2020a). Through CUP1, we found that interventions are often implemented in ad hoc and/or top-down ways, and they are not always tailored to the problem they are trying to solve. Rather than

develop and implement new interventions, which is costly and time-intensive, CUP1 recommended the optimisation of existing interventions, of which there are many. In realist terms, existing interventions probably only work for some doctors some of the time. We want to optimise the current situation, and build upon the time and money already invested by NHS Trusts, to ensure that existing interventions are more likely to work for more doctors more of the time, leading to a reduction of mental ill-health in doctors and ultimately to an improvement of patient care.

The CUP3 project seeks to address both of these gaps by considering the problem of doctors' mental health at work from multiple perspectives (e.g. individual, organisational, professional, social) and developing guidance for the implementation and refinement of existing interventions aimed at treating and preventing hospital doctors' mental ill-health.

2. RATIONALE

2.1. Why this research is needed now

Doctors' mental ill-health affects the individuals themselves, other doctors and healthcare professionals, and patients including both patient care and patient satisfaction (Wallace et al., 2009; West et al., 2014). The high incidence of mental ill-health in doctors, alongside related problems such as recruitment, retention, absenteeism, and presenteeism, has a clear impact on healthcare service delivery (Limb, 2015). In 2017, the House of Lords' Select Committee concluded that the lack of a long-term workforce strategy was "the biggest internal threat to the sustainability of the NHS" (House of Lords, 2017, p. 35). There is significant evidence showing a link between doctors' well-being, care provision and broader organisational performance (Kline, 2019; Wallace et al., 2009; West et al., 2011). Hospital settings that manage staff with respect and compassion have improved patient care and satisfaction, infection and mortality rates, Care Quality Commission ratings, and financial performance (Dixon-Woods et al., 2014). Similarly, managing staff with 'disrespect' can pose a threat to patient safety, as it undermines individual and team morale, collegiality, teamwork, and compliance with, and implementation of, new practices (Leape et al., 2012). This aligns with the conclusions of the GMC report on doctors' well-being (West and Coia, 2019)—revealingly titled "Caring for doctors, caring for patients"—and with our CUP1 findings (Carrieri et al., 2020b). In our CUP1 project, patients told us that the health of their doctors was important to them because: "if we want a healthy public, we also need a healthy workforce" (full video here: https://sites.exeter.ac.uk/careunderpressure/). The CUP3 project will help to ensure that the NHS is a great place to work (NHS England, 2019) and a world leader in creating work environments that care about doctors and other healthcare professionals.

The COVID-19 pandemic makes this research crucial and timely, not only because of the additional physical, professional, and psychological strain it has exerted on doctors (Greenberg et al., 2020), but also due to surges in workload of non-COVID-19 patient care (Bennett et al., 2020; Carrieri and Peccatori, 2020). Prior to the pandemic, 4.43 million people were waiting for treatment in February 2020, and this has since risen to 6.6 million in May 2022 (BMA, n.d.). In December 2020, 58% of 7000 UK doctors surveyed said that they were experiencing depression, anxiety, stress, burnout, emotional distress, or another mental health condition related to or made worse by their work or study (BMA, 2020). Another survey of more than 5000 UK doctors, conducted in April 2021, asked how doctors' career plans had changed for the next year (BMA, 2021): 32% said they were more likely to take early retirement, 25% said they were more likely to take a career break, and 21% said they were more likely to leave the NHS for another career. Notably, the reasons for changed career plans cited by doctors were: workload (45%), personal well-being (43%), pay (29%), working conditions (22%), the culture in their workplace (22%), and changed family/personal circumstances (20%) (BMA, 2021).

2.2. Care Under Pressure research to date

CUP1 was completed in 2020 and was the first realist review of interventions to tackle doctors' mental ill-health and its impacts on the clinical workforce and patient care in the UK. The methodology allowed us to synthesise diverse literature sources, and to engage iteratively with diverse stakeholders (e.g. doctors, patients, policy makers) to produce recommendations that support the tailoring, implementation, monitoring, and evaluation of contextually-sensitive strategies to address mental ill-health in doctors. The main findings of CUP1 (Carrieri et al., 2020b, 2020a) were:

- Doctors and medical students were more likely to experience mental ill-health when they felt isolated or unable to do their job, and when they feared repercussions of help-seeking.
- Interventions emphasising relationships and belonging were more likely to promote well-being.
- Interventions creating a people-focused working culture, balancing positive/negative performance, and acknowledging positive/negative aspects of a medical career helped doctors to thrive.
- Doctors and medical students needed to have confidence in an intervention for the intervention to be effective.

These findings are in line with a growing range of resources that promote doctors' well-being, at different levels (e.g. preventive, screening, and therapeutic) in the UK and internationally (Panagioti et al., 2017; Shanafelt and Noseworthy, 2017). Importantly, CUP1 identified key recommendations for refining/developing strategies to reduce mental ill-health and 10 high-level principles for use by those

refining/designing interventional strategies to tackle doctors' mental ill-health (Carrieri et al., 2020b, 2020a). A subsequent project, Care Under Pressure 2 (CUP2) is extending the CUP1 work to understand the situation for nurses, midwives and paramedics.

2.3. The proposed study (CUP3)

CUP3 enables the recommendations and principles developed in CUP1 to be implemented into practice. The project is designed to enable transferability to all NHS Trusts in the UK. Our research will address a vital need: to operationalise contextually sensitive and evidence-based principles to change workplace factors that are affecting doctors' well-being and patient care. It will underpin the important work of those organisations who support the NHS workforce, such as Health Education England (2019), the GMC (West and Coia, 2019), and NHS England (2019).

CUP3 aims to work with and learn from eight purposively selected NHS Trusts, building on the principles developed in CUP1, to develop an implementation toolkit for all NHS Trusts to help them reduce doctors' mental ill-health (including prevention) and its impacts on the workforce and patient care. To achieve the research aim, CUP3 will involve three sequential phases over 24 months, with each phase informing the next (see also

Figure 2).

- Phase 1: development of a typology of interventions to reduce doctors' mental ill-health. This will involve categorisation and analysis of the sources included in the CUP1 review and input from the project advisory group, and will inform the sampling for Phase 2.
- Phase 2: a realist evaluation of the existing combinations of strategies being used by NHS Trusts to reduce doctors' mental ill-health. This will involve 160 interviews with key stakeholders (e.g. NHS Trust doctors, service managers, occupational health) from eight NHS Trusts purposively sampled for contextual variation (e.g. size, doctors' well-being, geographical location).
- Phase 3: development of an implementation toolkit for all NHS Trusts to use to optimise their strategies to reduce doctors' mental ill-health, reducing the impact on the workforce and patient care. This will involve synthesising the insights from Phases 1 and 2 and input from the project advisory group and NHS Trust local stakeholders groups from Phase 2.

The exact design and components of the implementation toolkit will be developed iteratively through the project in collaboration with our project advisory group and NHS Trust local stakeholder groups. The toolkit will provide a framework for NHS Trust leaders and service managers to work with key stakeholders to assess and improve the effectiveness of their existing strategies to reduce doctors'

mental ill-health and its impact on patient care, with a focus on maintenance and sustainability of these strategies (Shelton et al., 2020). It will include practical guidance on how to optimise these strategies, considering the dynamic contexts and diversity of NHS Trusts. Dissemination of the project findings will involve standard and innovative forms, including cartoons and short videos, tailored to different audiences (e.g. doctors, NHS managers, policy makers, professional bodies).

The research outlined in this protocol relates primarily to Phase 2 – the realist evaluation – as this is the only phase collecting data from participants and thus requiring HRA Approval and ethical approval.

3. THEORETICAL FRAMEWORK

Building on CUP1, we are strongly committed to improving the mental health of doctors in their workplace, and, consequently, patient care. Donald Schön (1983) talked about the 'swampy lowlands' of professional practice, which he described as uncharted by evidence and incapable of technical solution. Given the messy reality of healthcare practice, we believe successful solutions will only be achievable if researchers co-create them with practitioners. Doing so draws on the implicit local and experiential knowledge of practitioners and participants in a way that acknowledges the full complexity of healthcare environments, policies, and processes.

In CUP1, we concluded that there are many interventions to prevent or ameliorate doctors' mental ill-health and that combinations of interventions are the norm. Therefore, any research that seeks to improve the interventions offered cannot study them in isolation, since they interact in a complex manner to produce their impacts. In addition, multiple local and national contexts influence the impact of these combinations of interventions and the research approach must take these into account. Therefore, studying the complex reality of the work environment (i.e. the combinations of interventions operating concurrently in any one hospital Trust, or ward of that hospital, rather than a controlled evaluation of a single intervention) will allow us to propose novel and workable solutions.

Acknowledging the complex reality of the interventions being used to support doctors in the NHS also means addressing the challenges of terminology. A wide range of terms are used to describe the problems facing the medical and wider healthcare workforce's well-being. In order to be inclusive and enable consideration of the complex reality of healthcare systems, this project considers a full spectrum of mental health and associated interventions, ranging from treatment for specific mental ill-health problems to preventative measures aiming to generally improve the mental health of the medical workforce. This will include interventions at different levels of the system, including individual, group, team, organisation, and national. Phase 1 focuses on developing a typology of interventions aiming to reduce doctors' mental ill-health and as part of this work, this terminology should become clearer.

Realist evaluation (Greenhalgh et al., 2015; Pawson and Tilley, 1997; Wong et al., 2017) enables us to understand the contextual conditions that make existing interventions work more or less well; develop transferable knowledge for delivery and impact that is sensitive to different settings within the NHS; and develop recommendations in real time that are relevant to our participating sites. A realist evaluation will generate an in-depth understanding of which components of the interventions currently being delivered by our participating NHS Trust study sites impact more (or less) than others, for whom, in which contexts, and in what respects. By using a realist, interpretive, theory-driven approach to analysing empirical data collected from the study sites, we will be able to move beyond description, to provide transferable findings that coherently explain how and why context can influence outcomes. A realist logic of analysis will be used to analyse and synthesise the data. This will involve iterative cycles of theory-building and testing to eventually produce a refined, NHS-specific version of the realist programme theory developed in CUP1. In other words, it will better explain how and why outcomes (intermediate, final, desired and undesired) might be achieved for the different interventions when they are used by NHS Trusts (i.e. what interaction between context and mechanism(s) might lead to those outcomes).

4. RESEARCH AIM

Our aim is to work with and learn from eight purposively selected NHS Trusts, building on the principles developed in CUP1, to develop an implementation toolkit for all NHS Trusts to optimise their strategies to reduce doctors' mental ill-health and its impacts on the workforce and patient care.

4.1. Objectives

1. Develop a typology of interventions to reduce doctors' mental ill-health and use this to inform sampling of eight NHS Trusts.
2. Work with the recruited Trusts to develop an explanatory account of whether and how their interventions are working, for whom, under what circumstances, in what respects, and why (or why not).
3. Use the findings to develop an evidence-based implementation toolkit that can be used across all NHS Trusts to inform the optimisation of the strategies used to reduce doctors' mental ill-health.

4.2. Outcomes

The main outcomes of CUP3 will be:

1. A typology of interventions to reduce doctors' mental ill-health (Phase 1).

2. A final CUP3 Programme Theory, and tailored and actionable guidance to improve the delivery of interventions to reduce doctors' mental ill-health in the eight recruited NHS Trusts (Phase 2).
3. An implementation toolkit for use by other NHS Trusts nationally to evaluate and optimise their strategies to reduce doctors' mental ill-health (Phase 3).

5. STUDY DESIGN AND METHODS OF DATA COLLECTION AND DATA ANALYSIS

Please note that this section through to section 8 relate to Phase 2 of the project, as this is the phase requiring HRA and ethical approval.

The plan of investigation will comply with the RAMESES II quality and reporting standards for realist evaluations (Greenhalgh et al., 2017; Wong et al., 2016). The project team have extensive experience in conducting realist research. The realist evaluation process will incorporate iterative cycles of data collection across the eight NHS Trusts. These cycles of realist analysis and engagement will lead to an in-depth understanding of which interventions are working (or not) for whom, in what circumstances, how, and why, which can then be used as the basis from which to develop evidence-based guidance.

5.1. Refining our initial programme theory

The goal of this step (informed by earlier work as part of Phase 1) is to refine our initial CUP3 programme theory of how interventions aiming to reduce doctors' mental ill-health are supposed to work (and for whom), when they do work, when they do not achieve the desired change in practice, why they are not effective, and why they are not being used (Wong et al., 2017). The rationale for this step is that interventions are 'theories incarnate'; that is, underpinning the design of such interventions are assumptions about why certain components are required. In other words, the designers of interventions have put them together in a certain way based on their theories about what needs to be done to get one or more desired outcomes (Pawson, 2013, 2006; Pawson and Tilley, 1997).

Our initial CUP3 programme theory will build on the programme theory developed through CUP1 and the typology developed during Phase 1 of CUP3. To further refine the initial programme theory we will undertake exploratory and informal searching of publications subsequent to the CUP1 realist review using citation tracking and snow-balling (Greenhalgh and Peacock, 2005), especially those involving empirical data collection in NHS Trusts. We will pay particular attention to research on the impact of COVID-19 on doctors, NHS Trusts, and patient care. An example of a paper that might contribute to the update of our programme theory is Bennet et al.'s (2020) qualitative research into the experiences and concerns of front-line NHS workers while caring for patients with COVID-19. We will consult with key content experts in our project advisory group representing multidisciplinary

perspectives and refine the initial programme theory further based on their feedback. We will have iterative discussions within the project team to make sense of and synthesise any new findings and project advisory group feedback into an initial coherent programme theory for CUP3.

5.2. Sampling

Eight NHS Trusts will be identified and recruited for the realist evaluation. We will initially purposively sample four NHS Trusts to generate some Context-Mechanism-Outcome configurations (CMOCs: the unit of analysis of realist methodology), and sample the remaining four to test and refine the CMOCs. This iterative purposive sampling strategy will maximise scope for contextual comparison of different Trusts in terms of size, geographical location, doctors' well-being, impact of COVID-19, ethnic diversity of both NHS staff and patients; and patient care. This will facilitate rigorous testing of our analysis, supporting the transferability of our results to other NHS Trusts. We anticipate there will be a benefit for sites signing up to the project because, through participating, we will co-develop tailored evidence-based guidance to improve their existing programmes of support, tackling doctors' mental ill-health and its impacts on the clinical workforce and patient care. We will then build on this guidance to develop the implementation toolkit for all NHS Trusts.

The NHS Trusts will be recruited iteratively throughout the project. However, we have already received letters of support from three Trusts – which vary in terms of their organisational size, geographical location, diversity of patients served and workforce, doctors' well-being figures, and impact of COVID-19 on service and staff. These Trusts are: Torbay and South Devon NHS Foundation Trust; Guy's and St Thomas' NHS Foundation Trust; and Hull University Teaching Hospitals NHS Trust.

Only Trusts in England will be sampled because there are healthcare system variations between England, Wales, Scotland and Northern Ireland, meaning that we would require a much larger number of participating Trusts to capture the structural and organisational diversity of the different countries. This would be beyond the scope of this work, making it difficult to capture enough data to make comparisons with eight Trusts, hindering the theory-building process. Focusing on one country supports more in-depth theory-building. These findings may prove to be transferable to other groups to a greater or lesser extent, when explored through future research.

At each NHS Trust site, we will evaluate the implementation and impacts of their existing interventions to improve the mental health of doctors. With support from the local Clinical Research Network we will identify a site lead and co-create a local stakeholder group (composed of doctors, service managers, and patients) at each NHS Trust site, which will champion our research and facilitate recruitment for the interviews.

The two key principles of the recruitment approach for this study are: (1) to take steps to minimise the burden upon the Trusts through a flexible approach, such as being flexible in the timings and locations of interviews and conducting online interviews; and (2) to sample inclusively to capture a broad range of experiences relevant to the interventions being used to support doctors.

5.3. Data collection

All data collection will be undertaken by the research fellows (AM, AP, CB), under the supervision of the Co-Chief Investigator (DC), with the support of the site leads at each NHS Trust.

5.3.1. *Interviews*

Realist interviews are a theory-driven type of qualitative interview and seek to validate, falsify or modify hypotheses about how interventions work (Manzano, 2016; Pawson, 1996; Pawson and Tilley, 1997). The aim of the interviews is to develop an explanatory account of whether/how interventions are working (or not), for whom, under what circumstances, how, and why, and to understand participants' insights about the different contexts, mechanisms and outcomes that may be important to promote well-being.

The interview guide will be developed iteratively throughout data collection, in alignment with the guidance for realist interviews (Manzano, 2016). This is to enable the questions asked to be developed as the research team's understanding of the issues develops through conducting the interviews and initial data analysis. The questions will develop across the course of the interviews to move through the three phases of realist interviewing (Manzano, 2016): (1) theory gleaning – developing the initial ideas about the interventions; (2) theory refinement – honing and improving theories, and identifying key theories; and (3) theory consolidation – fine tuning key theories. An initial topic guide has been developed with examples of the types of questions that we will be asking. This initial topic guide has been informed by the typology work of Phase 1 of the research and from the findings of CUP1's realist review.

We will undertake 160 qualitative realist interviews across the eight Trusts – approximately n=20 participants per NHS Trust. Participants recruited to participate in the interviews will include individuals working as hospital doctors within the eight NHS Trusts and staff involved with interventions to support doctors, such as human resources (HR) managers, service managers, well-being champions, occupational health, psychologists, chaplains, coaches, and other relevant staff involved in the design and delivery of support programmes, including those who are not Trust-based, e.g. the Practitioner Health Programme.

Interviews will be conducted by the research fellows and will last approximately 60 minutes, with earlier interviews in the process lasting longer than later ones as the theory consolidation phase progresses (Manzano, 2016). Interviews will be undertaken face-to-face where possible, or online using University of Exeter approved videoconferencing software (e.g. Zoom). Interviews will be recorded using encrypted digital recorders when conducted in person, and via the recording facilities of the video conferencing and using encrypted digital recorders for online interviews.

5.3.2. *Observations*

Prior to the interviews, where possible, the research fellows will also undertake workplace observations. These will not count as data but will be used to obtain background information about the interventions within an NHS Trust. Therefore, they will serve as an opportunity for the research fellows to familiarise with the Trust environments, helping them to conduct and interpret the interviews, and make best use of interview time; minimising the burden on the Trusts.

We expect that the types of observations deemed relevant will vary across sites. However, examples of the types of observations might include mental health and well-being hub management meetings, seminars/training sessions delivered by support services (e.g. PHP), and high-level management meetings about staff well-being (e.g. occupational health, staff well-being teams, practice development teams). We will not be observing doctors attending or receiving support interventions. Rather, the focus will be on understanding each Trust's approach to the provision of support for doctors, through obtaining further information about how the NHS Trust implements support for doctors or information about specific interventions. Observations will be documented through note taking. They will not be recorded or transcribed verbatim, nor will they identify any specific individuals.

5.3.3. *Document analysis*

Given the potential challenges engaging in observations, we will also be focusing on gathering additional information about each Trust's support interventions through document analysis. Based on our prior knowledge and engagement with the three Trusts that have already expressed an interest, we anticipate relevant documents might include: staff coaching and clinical psychology referral guidance; online staff well-being resources and other communications (posters, flyers, psychosocial staff support service updates, newsletters, Director of Workforce Briefings); and policy documents. These documents will supplement the interview data that we obtain, providing additional insights into the types of interventions available in each Trust and how and why these might be working (or not).

5.4. Data organisation and management

Full details of how data will be collected, processed and stored in the project are outlined in the 'CUP3 Data Management Plan v1.0 20221108'.

Data will be stored on password protected and encrypted University laptops on the University of Exeter's OneDrive for Business. Encrypted digital recorders will be used to record the interviews. Audio recordings will be retained until they have been transcribed and will then be destroyed. Individual files containing personal information will be password protected, where the software enables this. Paper copies of data will be stored in locked filing cabinets, until they can be transferred to an electronic format, after which they will be destroyed. Only the minimum number of individuals required will have access to identifiable data. Some members of the research team are from the University of Oxford and Hull York Medical School. If data is shared with them for the purposes of analysis or other research activities, then this will be done via the sharing functionality in the University of Exeter's OneDrive for Business.

Only the research team will have access to the research data in the OneDrive for Business environment. All research team members will comply with the requirements of the GDPR 2018 (now UK GDPR) with regard to data collection, storage, processing, and disclosure of any personal information. Any personal information will be kept strictly confidential and will not be disclosed outside the research team.

The interview data will be transcribed verbatim by a professional transcription service. Standard contracts will be in place with the company, including agreement to data management and protection, including confidentiality, and data will be transferred securely. At the point of transcription, identifying information will be indicated for later de-identification by the research team (e.g. using asterisks).

For the purposes of data archiving, data will be de-identified using the guidance provided by the UK Data Archive 'Managing and Sharing Data' document (Corti et al., 2011). For example, removal of direct identifiers (e.g. names), using aggregated categories (e.g. age in years instead of date of birth), and generalising the meaning of detailed text (e.g. replacing a doctor's detailed area of medical expertise with an area of medical speciality). De-identification in the transcripts will be indicated with [brackets]. A log of all de-identification activities will be made and stored separately from the research data.

The de-identified research site data, demographic data, and transcripts will be deposited in the UK Data Service's ReShare platform (https://reshare.ukdataservice.ac.uk/). Access controls will be in place to protect participant data, which cannot be anonymised without losing the utility of the data.

The data will be deposited using the 'Safeguarded' data option, meaning that researchers have to register and agree to the UK Data Service's End User Licence (https://dam.ukdataservice.ac.uk/media/455131/cd137-enduserlicence.pdf) before they can access the data. We would also add the additional control of researchers requiring the depositor's permission to access the data, and the user would need to sign a Data Sharing Agreement (drawn up by the University of Exeter's Legal team). Therefore, while the data is available for sharing with other researchers, it will not be open access.

5.5. Data analysis

Data analysis will be concurrent with data collection, in line with realist interviewing conventions (Manzano, 2016). Data analysis will help us understand and explain why the interventions in these eight Trusts have had the impacts observed, how, for whom, in which circumstances and to what extent. This will allow us to develop an in-depth, realist understanding and explanation of the impacts observed. Each new element of relevant data will be used to refine aspects of the programme theory, and as it is refined, data sources will be re-scrutinised to search for data relevant to the revised programme theory that may have been missed initially.

Transcripts will be uploaded to NVivo for analysis. Relevant sections of transcripts that have been interpreted as related to contexts, mechanisms and/or their relationships to outcomes will be coded within NVivo. This coding will be both inductive (codes created to categorise data identified through the analysis process) and deductive (codes created in advance of data extraction and analysis as informed by the initial programme theory). Underpinning the coding will be retroduction, which is the process of unearthing causal mechanisms, and a key analytical process in realist methodology (Jagosh, 2020).

Specific characteristics of the eight Trusts and the multiple interventions will be extracted separately into an Excel spreadsheet to provide a descriptive overview. Descriptive statistics of the participants who took part will be study will be used to describe the sample at group levels (so no individual participant will be identifiable).

5.6. Synthesising the evidence

Data analysis will use realist logic to make sense of the initial programme theory. A realist logic of analysis builds causal explanations in the form of context-mechanism-outcome configurations (CMOCs) for the programme theory. To achieve this, the data will be interpreted to ascertain if it pertains to context (C), mechanism (M), outcome (O), the relationships between C, M, and O, and/or the relationships between CMOCs (Pawson, 2006). In addition, during the analysis we will use

interpretive cross-case comparison to understand and explain how and why observed outcomes have occurred, for example, by comparing interventions where reducing mental ill-health has been deemed 'successful' in some Trusts against those which have not (based on self-report and any other routinely collected data), to understand how context has influenced reported findings. This type of analysis will enable us to understand the behaviour of the most relevant and important mechanisms under different contexts, thus allowing us to build more transferable CMOCs. During the research, we move iteratively between the analysis of particular examples from the data, refinement of programme theory, and further iterative data analysis to test particular subsections of the programme theory. The realist evaluation will follow current quality and publication standards (Wong et al., 2017). Finally, when making sense of our data during analysis we will use the following analytic concepts (Pawson, 2013, 2006):

1. Juxtaposition of sources of evidence – for example, where evidence about behaviour change in one data source enables insights into evidence about outcomes in another source.
2. Reconciling of sources of evidence – where findings differ in apparently similar circumstances, further investigation is appropriate in order to find explanations for why these different results occurred.
3. Adjudication of sources of evidence – on the basis of methodological strengths or weaknesses.
4. Consolidation of sources of evidence – where outcomes differ in particular contexts, an explanation can be constructed of how and why these outcomes occur differently.

This process will allow us to explore why some interventions might work well for some doctors and in some settings, but not others. We will then use this in-depth understanding and explanation as a starting point of our discussions with the stakeholders at each NHS Trust site. In effect, our refined programme theory provides us, for each site, a 'diagnosis' of which intervention is working well (or not), for whom, under what circumstances and why that can then be used as the basis from which to develop improvements. We will look at specific interventions, e.g. one at each 'level' (individual, organisational, etc.), highlight their interdependencies, and develop an explanatory account of whether/how these initiatives are working, for whom, under what circumstances and why. We will also work with the stakeholders at each NHS Trusts to develop transferable learning points which can help all Trusts to improve their strategies to reduce doctors' mental ill-health.

5.7. Drawing conclusions

The main outputs from Phase 2 will be: 1) a refined CUP3 programme theory and; 2) evidence-based and tailored guidance for each participating NHS Trust (written for Trust leads, service managers, and

doctors) on how they can improve their implementation of interventions to reduce doctors' mental ill-health, and its impacts on the clinical workforce and patient care. We will use the findings to develop a first draft of the implementation toolkit in Phase 3.

6. STUDY SETTING

The research sites will be eight NHS Trusts in England. The sample will aim to incorporate a range of Trusts offering a variety of support interventions and strategies for doctors and a variety or organisational contexts. The typology development work from Phase 1 will be used to inform selection of the eight NHS Trusts. Therefore, the sample of eight Trusts will be purposively chosen to ensure that they represent a range of different characteristics to support theory-building. In addition, the NIHR Clinical Research Network (CRN) will be drawn upon to help identify NHS Trusts and key contacts within them. Dr Pauline McGlone (Deputy Chief Operating Officer of the NIHR CRN South West Peninsula) is also a member of the project steering group. Only Trusts in England will be sampled to enable better theory-building; the healthcare system variations between England, Wales, Scotland and Northern Ireland would require a much larger number of participating Trusts to capture the structural and organisational diversity.

Participants will be accessed for interviews at each NHS Trust (research site) through the NHS Trust local stakeholder groups, who will act as local collaborators within each research site. These site leads at each of the recruited eight NHS Trusts will support the project by facilitating recruitment and engagement with the research project. For example, they will act as gatekeepers to communication within each Trust, e.g. circulation of recruitment emails. They will also be able to advise on appropriate activities for the research fellows to observe and share relevant documentation from their Trust.

7. SAMPLE AND RECRUITMENT

7.1. Eligibility Criteria

We will be recruiting staff working within the eight NHS Trusts either as doctors in hospital settings, or as staff involved in the design and delivery of support interventions. The recruitment strategy will be as inclusive as possible. The recruitment strategy will also be flexible to enable adaptation to the specific needs and contexts of the different NHS Trusts.

7.1.1. *Inclusion criteria*

We will include all doctors working in hospital setting during the time of our research (this will potentially include community doctors deployed in acute care during the pandemic and any other

community doctor who works in a hospital setting, such as those in triage roles within Emergency Departments or GP trainees in acute settings).

We will also include staff with roles that involve the design and delivery of support interventions for doctors. This may include: human resources managers, service managers, well-being champions, occupational health, psychologists, chaplains, coaches, and other relevant staff. This may also include staff from well-being services used by the eight NHS Trusts but delivered by non-NHS organisations, e.g. the Practitioner Health Programme.

Only those aged 18 years or older will be included. Only those working within (although not necessarily employed by) the eight recruited NHS Trusts will be eligible for inclusion.

7.1.2. *Exclusion criteria*

Medical students will not be recruited into the study. Doctors working in non-hospital settings will not be recruited to the study.

7.2. Sampling

7.2.1. *Size of sample*

We will undertake 160 qualitative realist interviews across the eight Trusts – approximately n=20 participants per NHS Trust. This sample size has been determined by the realist methodologists within the research team as sufficient to support theory building by sampling a range of individuals within and across the eight NHS Trusts, whilst maintaining a manageable scope.

7.2.2. *Sampling technique*

Eight NHS Trusts identified in Phase 1 will be recruited for Phase 2. We will initially purposively sample four NHS Trusts to generate some CMOCs (the unit of analysis of realist methodology). The first four NHS Trusts will likely include the three Trusts who have expressed support for the project and one other, which has not yet been selected. We will then sample the remaining four Trusts to test and refine the CMOCs. This iterative purposive sampling strategy aligns with sampling approaches in realist methodology (Emmel, 2013). It will maximise scope for contextual comparison of different Trusts in terms of size, geographical location, doctors' well-being, impact of COVID-19, ethnic diversity of both NHS staff and patients; and patient care. This will facilitate rigorous testing of our analysis, supporting the transferability of our results to other NHS Trusts.

7.3. Recruitment

With support from the local NIHR CRN we will identify a site lead and co-create a local stakeholder group (composed of doctors, service managers, and patients) at each NHS Trust site. These groups will champion the research and facilitate recruitment for the interviews.

7.3.1. *Sample identification*

The local stakeholder groups at each NHS Trust will act as gatekeepers for the research. Participants will be recruited using email invitations and a recruitment poster advertising the research. The local stakeholder groups will use their networks within the Trust to circulate recruitment emails to relevant groups of staff. These emails will advertise that the study is taking place, outlining the purpose of the research, and inviting doctors and staff involved in the design and delivery of support interventions for doctors to contact the researchers if they are interested in participating. Therefore, participants will be identified and recruited by their professional roles, and those with an interest in improving the workplace support available in their Trust can participate in the study. A poster advertising the research will be circulated as an attachment to the recruitment emails and also printed by the local stakeholder groups and displayed in appropriate areas of the Trust. The research may also be advertised through each Trust's local communication channels (e.g. social media, intranet, at training sessions) using the recruitment poster. These additional methods will be advised by, and occur through, the local stakeholder groups at each NHS Trust.

Participants will be given a voucher (e.g. One4All) worth £20 for their participation in a research interview, which will be supplied through University of Exeter processes. The voucher will be emailed to the participant following the interview.

7.3.2. *Consent*

The data collection process for the interviews is displayed visually in Figure 3. When potential participants express an interest in participating by emailing the research team, then they will be sent the Participant Information Sheet as a PDF attachment and be given the opportunity to ask questions and/or discuss this further. If, having read the information and asked any questions, they are happy to proceed, a date, time and location for the interview will be arranged. Prior to the interview, the participant will be sent the Consent Form to read. At the interview, the researcher will go through the Participant Information Sheet and the participant will be given the opportunity to ask any further questions about the research. The Participant Information Sheet and Consent Form have both been developed in accordance with HRA guidance.

For in person interviews, the Consent Form will be completed online via Microsoft Forms. The researcher will display the Consent Form to the participant on their laptop screen. They will read through together and the researcher will complete the form, taking verbal consent from the participant. A PDF of the Consent Form will be saved and emailed to the participant after the interview. In the event of technical issues, such as no internet, a paper Consent Form will be completed by both the participant and researcher.

For online interviews, the Consent Form will be completed online via Microsoft Forms. The researcher will display the Consent Form to the participant via screen sharing. They will read through together and the researcher will complete the form, taking verbal consent from the participant. A PDF of the Consent Form will be saved and emailed to the participant after the interview.

8. ETHICAL AND REGULATORY CONSIDERATIONS

8.1. Assessment and management of risk

8.1.1. *Potential for distress*

The focus of the research is on the interventions within NHS Trusts designed to support doctors' mental health, either through treatment or prevention. This will include interventions at different levels of the system, including individual, group, team, organisation, and national. Doctors are being recruited in relation to their professional role as doctors working in hospital settings. They are not being recruited because they have experience of mental health problems. The questions in the interviews will not be focused on doctors' personal experiences of mental health, but rather on their perceptions of the interventions to support doctors' well-being in their Trust. Nonetheless, some doctors who choose to participate might have experienced mental health problems, since these are prevalent amongst healthcare professionals. Therefore, there is potential for some doctors to become upset or distressed during the interviews.

The interviews will be conducted by the three research fellows, each with experience in interviewing and understanding of the topic area. The research fellows will pay attention to the demeanour of the research participants and be aware of the possibility for participants to become upset or distressed. In these instances, the researchers would ask the participant if they wish to end the interview. The interview will not continue unless the participant gives a clear indication that they are comfortable doing so. If a participant does not wish to answer a question, then they do not have to. If appropriate, the research fellows will advise the participant to contact their local support systems. These local support systems will vary between Trusts, and one of the roles of the NHS Trust local stakeholder groups will be to advise the research team where participants should be directed for further support.

This information will also be included in the Participant Information Sheet, adapted for each NHS Trust. Participants will also be reminded of their right to withdraw throughout the research.

8.1.2. *Burden*

A potential burden for research participants will be the time commitment they would need to give for the research. Details on the time commitment will be provided in the recruitment materials prior to consenting to participate.

8.1.3. *Breaking confidentiality*

In the highly unlikely event of data being disclosed that is deemed a safeguarding concern for the participant or others, or a patient safety concern, it may be necessary to break confidentiality. In such instances, the research fellow will contact the Co-Chief Investigators (DC or KM), who will assess appropriate action on a case-by-case basis. The research team may be obliged to contact the appropriate lead (advised by the NHS Trust local stakeholder group). This information will be communicated within the Participant Information Sheet.

8.2. Research Ethics Committee (REC) and other Regulatory review & reports

This study involves NHS staff recruited via the NHS (Phase 2), so the study requires Health Research Authority (HRA) approval. While research with NHS staff does not necessarily require NHS REC approval, the topic and nature of the research make it seem suitable for NHS REC ethical approval, so this will be sought alongside the HRA application. The study and data collection will only commence once both the HRA approval and NHS REC approval have been granted.

All correspondence with the HRA and NHS REC will be retained for the duration of the study. The Co-Chief Investigators will notify the HRA and NHS REC when the study concludes and any premature terminations; it is also the Co-Chief Investigators' responsibility to produce annual reports if required, and a final report with the results including any publications/abstracts.

When both HRA approval and NHS REC approval have been obtained, then local site approval will be sought via the HRA's Capacity and Capability Approval processes and NHS R&D Department sign-off.

8.3. Amendments

Substantial and non-substantial amendments will be notified to the HRA and NHS REC for consideration after clearance from the Sponsor. The Sponsor will be responsible for deciding whether an amendment is substantial or non-substantial. Once approved, all amendment details will be notified to participating sites. All amendment communications will be kept for the study duration and

the amendment history table detailed in Appendix 3 will be used to ensure the most up to date protocol is available.

8.4. Peer review

The research, including the protocol, has gone through several different review processes.

The research is funded by an NIHR HS&DR grant, for which the research proposal went through two stages of review by the NIHR HS&DR review panels, which have varied composition (e.g. researchers, PPI, NIHR managers). Some changes were suggested by the committee which have been incorporated into the study design. Overall the feedback was excellent. The grant application was also reviewed by PPI stakeholders from CUP1 and the NIHR South West Research Design Service (RDS).

The research has also been reviewed within the research team (which includes methodological experts) from the Universities of Exeter, Oxford, and Hull York Medical School. It has also been reviewed internally at the University of Exeter by the Research Governance Manager (Lead Sponsor), as part of the research governance process.

8.5. Patient & Public Involvement

The design of this research was strongly informed by our continuous engagement with the stakeholder group from CUP1, which is becoming the project advisory group for CUP3 (and complements the CUP3 NHS Trust local stakeholder groups). DC discussed the CUP3 project idea with three patients in the nascent project advisory group and two of them also provided feedback on the successful NIHR grant application.

The NIHR grant application was critically reviewed by the South West RDS, including their PPI representatives and advisors. The feedback they provided included being pleased that our intended PPI group included not only patients but also doctors, including trainees, since they are key beneficiaries. The feedback from PPI representatives also suggested that we should include representation from NHS Trust managers, as many mental health issues may be systemic and this suggestion was incorporated in the design of the research. NHS managers will have in depth knowledge of contextual barriers and facilitators to optimise support interventions in the workplace and may see different kinds of possible solutions.

The CUP3 project will involve three groups: project steering group; project advisory group; and NHS Trust stakeholder groups (as outlined above under ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS AND INDIVIDUALS). The core research team will work with the three groups throughout the course of the research. In particular, all three phases of CUP3 (including Phase 2, to which this application relates) will be supported by our project advisory group to provide

content expertise for programme theory refinement. We will engage our project advisory group in relation to:

- Development and refinement of the typology of interventions (Phase 1)
- Guidance for additional literature that may be relevant to the project (Phases 1-3)
- Guidance on purposive sampling and recruitment of eight NHS Trusts (Phase 1-2)
- Development of a feasible and practical implementation toolkit (Phase 3)
- Development and optimisation of engagement materials (Phase 3)
- Dissemination of academic articles and other outputs to different audiences (Phase 3)

The project advisory group will feed into the study via six main meetings. Meetings will be held at strategic moments of each phase so that the group can provide input at key stages, and each meeting will last approximately 2 hrs. We will work with members of the group prior and after each meeting to ensure they feel well supported and have had the chance to share their ideas and opinions. Patients will be paid for participation and appropriate expenses (e.g. travel, accommodation) in each meeting in line with INVOLVE guidance.

8.5.1. *Training and impact of PPI*

We anticipate the members of the project advisory and stakeholder groups will not require extensive training. However we will provide briefing and training if required (e.g. on realist methods), with support from the well-established PenARC public involvement experts and training resources. The PPI co-leads (DC and JH) will act as the point of contact for all PPI activities (related to both project advisory and site specific stakeholder groups), will brief the PPI members on how the meetings will work and support them with any concerns they may have (as during CUP1). The impact of PPI will be captured, evaluated and reported using an impact log approach to gather and store information, which will be shared and discussed regularly by the research team.

8.6. Protocol compliance

This study will be carried out in accordance with the proposed protocol. Any protocol deviations, non-compliances, or breaches will be considered as departures from the approved protocol. Accidental protocol deviations can happen at any time. However, should any accidental deviations occur, they will be adequately documented on the relevant forms and reported to the Sponsor and relevant HRA Amendment Team. Frequent deviations will require immediate action and could potentially be classified as a serious breach if not addressed.

8.7. Data protection and patient confidentiality

Full details of how data will be collected, processed and stored in the project are outlined in the 'CUP3 Data Management Plan v1.0 20221108'.

Participants' and contributors' confidentiality will be maintained through the application of procedures in line with the General Data Protection Regulations (GDPR) 2018 (now UK GDPR). All research team members will comply with the requirements of the GDPR 2018 with regard to data collection, storage, processing, and disclosure of any personal information. Any personal information will be kept strictly confidential and will not be disclosed outside the research team. Only the minimum number of individuals required will have access to identifiable data. All information containing personal information will be stored securely on password protected and encrypted University laptops and/or in locked filing cabinets.

No individual will be identified by name in any dissemination output. All identifiable details, such as names, will be removed from the data through the application of pseudonyms/codes to protect participant confidentiality. Participants will also be assigned unique study participant numbers to protect their confidentiality.

For the purposes of data archiving, data will be de-identified using the guidance provided by the UK Data Archive 'Managing and Sharing Data' document (Corti et al., 2011). For example, removal of direct identifiers (e.g. names), using aggregated categories (e.g. age in years instead of date of birth), and generalising the meaning of detailed text (e.g. replacing a doctor's detailed area of medical expertise with an area of medical speciality). De-identification in the transcripts will be indicated with [brackets]. A log of all de-identification activities will be made and stored separately from the research data.

The de-identified research site data, demographic data, and transcripts will be deposited in the UK Data Service's ReShare platform (https://reshare.ukdataservice.ac.uk/). Access controls will be in place to protect participant data, which cannot be anonymised without losing the utility of the data. The data will be deposited using the 'Safeguarded' data option, meaning that researchers have to register and agree to the UK Data Service's End User Licence (https://dam.ukdataservice.ac.uk/media/455131/cd137-enduserlicence.pdf) before they can access the data. We would also add the additional control of researchers requiring the depositor's permission to access the data, and the user would need to sign a Data Sharing Agreement (drawn up by the University of Exeter's Legal team). Therefore, while the data is available for sharing with other researchers, it will not be open access.

The de-identified data deposited on the UK Data Services online data repository, ReShare, will be preserved for ongoing sharing with other researchers. The remaining research data will remain the property of the University of Exeter and the Co-Chief Investigator (DC) will remain the custodian. The data will be stored for a minimum period of 10 years in line with the University of Exeter Research Ethics Policy.

In the highly unlikely event of data being disclosed that is deemed a safeguarding concern for the participant or others, or a patient safety concern, it may be necessary to break confidentiality. In such instances, the research fellow will contact the Co-Chief Investigators (DC or KM), who will assess appropriate action on a case-by-case basis. The research team may be obliged to contact the appropriate lead (advised by the NHS Trust local stakeholder group). This information will be communicated within the Participant Information Sheet.

8.8. Indemnity

Insurance and indemnity to meet the legal liability for harm to participants arising from the design, management, and conduct of the research is covered by the University of Exeter's insurers.

8.9. Access to the final study dataset

The research team will have access to the final dataset. If participants request a copy of their data, then this will be provided to them.

Due to ethical concerns relating to the potential identification of individuals, the research data supporting this publication will not be made publicly available, but will be available on request through the UK Data Services online data repository, ReShare.

It should be noted that all quotes in dissemination outputs will be anonymised to protect the participant and their workplace and employing organisation.

9. DISSEMINATION POLICY

9.1. Dissemination policy

We want to ensure that CUP3's outputs will be useful to the NHS, and tackle doctors' mental ill-health and its impacts on the clinical workforce and patient care. So will ask our project advisory group for their help to ensure the utility and relevance of the project's outputs and overcome implementation barriers. The project will produce five types of output. We will consult with our project advisory group, and, if possible the NHS Trust local stakeholder groups, and use their knowledge and experience to refine the development, presentation and dissemination of these outputs:

1. *Implementation toolkit for NHS leaders, service managers and doctors*. We will co-create an evidence-based doctors' mental health support implementation toolkit aimed at NHS Trusts in England. As part of the development process of this toolkit we will also develop tailored and actionable guidance to improve the delivery of interventions to reduce doctors' mental ill-health in the eight recruited NHS Trusts. Our primary audience will be NHS senior managers, Royal Colleges, and national policy makers but will also include any other groups that our stakeholders tell us are important. The exact design and components of the implementation toolkit will be developed iteratively in collaboration with our project advisory group (including our PPI members) and NHS Trust local stakeholder groups, but are likely to include innovative forms of communication (see 4 and 5 below). This will achieve impact over the medium- to longer-term (1-5 years) once policy makers, NHS managers/leaders, and organisations supporting doctors are able to implement changes and evaluate the impact of those changes.

2. *Conventional academic outputs*. A report for publication in NIHR Journals; at least two manuscripts for publication in a high-impact peer-reviewed journal (e.g. BMJ, JAMA, or Journal of Health Services Research & Policy); conference presentations (e.g. Health Systems Global, Health Services Research UK). This will achieve impact over the longer-term (3-5 years) through informing the agenda for debate and action in health services and in public policy more widely.

3. *Plain English summaries.* The research findings would be tailored to different audiences (e.g. doctors, patients, health service managers, medical educators, policy makers). This will achieve impact in the short- to medium-term (1 month to 2 years) by providing a meaningful summary of findings which increase stakeholders' recognition and understanding of the issue and how evidence can inform actions they can take.

4. *More innovative forms*. We have had positive experiences of involving graphic artists to help with the communication of the CUP1 findings. Therefore, depending on the results of the realist evaluation, we propose to translate some of our outputs into comics, animations and/or information graphics that might be distributed more widely (e.g. for notice boards on wards, inductions, teaching sessions) to help disseminate the implementation toolkit. See Figure 4 below for an example cartoon from CUP1 (please visit https://sites.exeter.ac.uk/careunderpressure/ for more information and examples).

Figure 4. Example cartoon from CUP1.

5. *Media engagement strategy*. We anticipate that more traditional forms of dissemination (e.g. peer-reviewed publication) will be ineffective in reaching some groups but other routes (e.g. Royal Colleges, UK Foundation Programme Office, Health Services Journal, Pulse, Politics Today, The Conversation, Twitter) may work better for these. This will achieve impact in both the short- and long-term by *raising awareness,* informing public and professional understanding and stimulating debate on a large-scale, changing how the issue is understood at a policy level, mobilising public opinion and professional groups to take action informed by the findings. We will use our existing highly accessed CUP website (https://sites.exeter.ac.uk/careunderpressure/), to maximise engagement with the project and its findings, and to encourage further debate. We will consult experienced communications officers at the Universities of Exeter, Oxford, and Hull York Medical School for additional support to refine these and they will be invited to the project advisory group meetings in the second half of the project. The CUP website is also linked to the CUP Twitter account (@care_under) which has been and will continue to be used to disseminate outputs.

The expertise of the project team and the project advisory group will be key to the creation of appropriate outputs. We will share our findings and outputs via presentations, newsletters, websites and blogs (e.g. NIHR blogs, BMJ Opinion, CUP website), peer-reviewed journals, social media (e.g. via the CUP Twitter account @care_under); conferences, and relevant meetings/seminars. To help bring to life our findings, and inform positive changes to existing mental health support, we will work with cartoonists and animators throughout the lifecycle of the project to make our guidance more accessible and impactful. We learnt from CUP1 the importance of engaging with artists who are already invested in the topic area (in CUP1 our two artists were a GP and a patient); and of starting the dialogue as early as possible in the project to allow appropriate time for the collaboration and creative ideas to develop (Carrieri et al., 2020b).

9.2. Authorship eligibility guidelines and any intended use of professional writers

The Co-Chief Investigators and co-investigators will be granted authorship where warranted on the final study report and manuscripts submitted for publication.

There is no intention to use professional writers.

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11. APPENDICES

11.1. Appendix 1 – Required documentation

List here all the local documentation you require prior to initiating a participating site (e.g. CVs of the research team, Patient Information Sheet (PIS) on headed paper etc.).

- CVs of the research team
- Participant information sheet with Trust specific details
- Email advert
- Poster
- Letter of Access for each researcher attending a site
- Organisation Information Document

11.2. Appendix 2 – Schedule of Procedures

Procedures	Research component	
	Recruitment	Interview
Participant information sheet	x	x
Informed consent		x
Demographics survey		x
Interview		x

11.3. Appendix 3 – Amendment History

List details of all protocol amendments here whenever a new version of the protocol is produced. Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC.

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made