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How can NHS trusts in England optimise strategies to improve the mental health and well-being of hospital doctors? The Care Under Pressure 3 (CUP3) realist evaluation study protocol

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ABSTRACT

Introduction The growing incidence of mental ill health in doctors was a major issue in the UK and internationally, even prior to the COVID-19 pandemic. It has significant and far-reaching implications, including poor quality or inconsistent patient care, absenteeism, workforce attrition and retention issues, presenteeism, and increased risk of suicide. Existing approaches to workplace support do not take into account the individual, organisational and social factors contributing to mental ill health in doctors, nor how interventions/programmes might interact with each other within the workplace. The aim of this study is to work collaboratively with eight purposively selected National Health Service (NHS) trusts within England to develop an evidence-based implementation toolkit for all NHS trusts to reduce doctors' mental ill health and its impacts on the workforce.

Methods and analysis The project will incorporate three phases. Phase 1 develops a typology of interventions to reduce doctors' mental ill health. Phase 2 is a realist evaluation of the existing combinations of strategies being used by acute English healthcare trusts to reduce doctors' mental ill health (including preventative promotion of well-being), based on 160 interviews with key stakeholders. Phase 3 synthesises the insights gained through phases 1 and 2, to create an implementation toolkit that all UK healthcare trusts can use to optimise their strategies to reduce doctors' mental ill health and its impact on the workforce and patient care.

Ethics and dissemination Ethical approval has been granted for phase 2 of the project from the NHS Research Ethics Committee (REC reference number 22/WA/0352). As part of the conditions for our ethics approval, the sites included in our study will remain anonymous. To ensure the relevance of the study's outputs, we have planned a wide range of dissemination strategies: an implementation toolkit for healthcare leaders, service managers and doctors; conventional academic outputs such as journal manuscripts and conference presentations; plain English summaries; cartoons and animations; and a media engagement campaign.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This research builds on earlier stages of the Care Under Pressure evidence-based and system-level research to optimise how National Health Service (NHS) trusts address workplace mental ill health (including preventative promotion of well-being).
⇒ Sampling and recruitment strategy that aims to maximise diversity and inclusivity.
⇒ Engagement of different audiences (eg, doctors and healthcare leaders) to support the development of contextually sensitive workplace strategies.
⇒ The findings may not be transferable beyond the UK hospital doctor context, yet we know research is also needed in other health professions, in primary care settings and beyond the UK.
⇒ Phase 2 focuses only on acute NHS trusts/secondary care. While this excludes other types of NHS trusts, focusing on one setting allows in-depth research into key social, structural and organisational factors.

INTRODUCTION

The growing incidence of mental ill health in doctors was a major issue in the UK and internationally, even prior to the COVID-19 pandemic.[1–3] This problem has significant and far-reaching implications, including; poor quality or inconsistent patient care, absenteeism, workforce attrition and retention issues, presenteeism, substance addiction, and increased risk of suicide.[4 5] The recent COVID-19 pandemic makes research into how to address this issue more crucial and timely, not only because of the additional physical, professional and psychological strain it has exerted on doctors,[6] but also due to surges in workload of non-COVID-19

patient care.[7 8] Addressing mental ill health in doctors is vital to the sustainability of health services.[9 10]

The urgency and salience of the problem of mental ill health in doctors, even before COVID-19, is reflected by the growing number of systematic reviews and primary research studies[11] opinion pieces,[12] recommendations[13] and doctors' memoirs.[14] Feelings of isolation and lack of job control have been identified as major causes leading to mental ill health in doctors.[11 15] Evidence suggests that both individual doctors and organisations have a role to play in addressing the issue of mental ill health.[11] Although all health services aim to keep their staff healthy, in the UK one of the main objectives of the 2020/2021 National Health Service (NHS) People Plan (which sets out guidelines for employers and systems within the NHS) is 'to keep our people safe, healthy and well—both physically and psychologically' (p6[16]). However, in 2021, the NHS Staff Survey found 46.8% of staff reported feeling unwell as a result of work-related stress, increasing from 38.4% in 2017. 54.5% said they had gone to work in the last 3 months despite not feeling well enough to perform their duties, and 31.1% said that they often think about leaving the NHS.[17]

There is a significant evidence showing a link between doctors' well-being, quality and safety of care provision, and broader organisational performance.[18–20] Hospital settings that manage staff with respect and compassion are associated with better patient care and satisfaction; infection and mortality rates; Care Quality Commission (CQC) ratings and financial performance.[21] 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.[22] This is in line with the conclusions of the 2019 General Medical Council (GMC) report on doctors' well-being[23] and other research findings.[24] The protocol presented here for the Care Under Pressure 3 (CUP3) study would underpin and drive improvements, and make a major difference to how doctors' workplace well-being in the NHS can be achieved and sustained, in line with achieving the NHS's long-term plan aim of 'making the NHS a consistently great place to work' (p86[25]).

Mental ill health in doctors is unlikely to improve unless two important gaps in relevant research and practice are addressed. First, most research is undertaken within disciplinary silos without simultaneously considering the many dimensions (individual, organisational, professional, etc) that may negatively affect doctors' well-being.[26] The emphasis on resilience (and in the COVID-19 period on heroism[27]) 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.[28–31] Second, there is a lack of guidance on how to implement existing recommendations in organisational settings, to ensure they work in the ways intended, that is, how to put theory into practice.[15] Existing workplace support for doctors seems to be having limited effect in resolving the known problems, and interventions often do not take into account the many different facets contributing to mental ill health.

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 National Institue for Health and Care Research (NIHR)-funded CUP1 review[15]—brought together evidence, and produced guidance and recommendations to reduce doctors' mental ill health in the workplace. One conclusion from CUP1 was that we do not need more initiatives, but we need to improve the ones that we already have. CUP1 found that interventions were often implemented in ad hoc and/or top-down ways and were not always tailored to the problem they were trying to solve. Rather than develop and implement new interventions, which are 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. CUP2 is still in progress, and extends the CUP1 work to include nurses, midwives and paramedics.

CUP3 builds on CUP1 and CUP2.[32] Thus, CUP3 addresses 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.

We are using the term 'mental ill health' within this protocol as an umbrella term to encompass the wide range of interventions that address the mental and emotional well-being needs of doctors. We aim to capture the spectrum of preventative measures and optimising well-being through to the treatment of mental illness.

The focus on hospital doctors reflects the fact that NHS trusts (ie, secondary care) are the largest employers of doctors, together with the significant potential for sick doctors to cause harm to patients and the financial implications of doctors' mental ill health.[26] Similar studies are needed in primary care settings and beyond the UK but, given the significant structural and organisational diversity between primary and secondary care, this is beyond the scope of the current study. Focusing on one staff group in one aspect of healthcare delivery allows us to conduct more in-depth research into specific social, structural and organisational elements, which we know to be important, and ensure that our findings will be relevant to hospital doctors and management. These findings may prove to be transferable to other groups to a greater or lesser extent, when explored through future research.

METHODS

Study aims

Our aim is to work with and learn from eight purposively selected NHS trusts, building on evidence-based principles previously published,[15] 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.

Research questions

1. How can workplace mental health and well-being interventions for doctors be conceptualised in a way that enables application of a consistent typology?
2. What works, for whom, in what circumstances, how and why (not) to support doctors' mental health and well-being within acute NHS trusts?
3. What are the optimal components of a toolkit that would facilitate NHS trusts' implementation of evidence-based strategies to reduce doctors' mental ill health?

Study design

To achieve the research aim, we will undertake three sequential phases of research activity, mapping to the three research questions above, with each phase informing the next (figure 1).

- Phase 1 aims to develop a typology of interventions to reduce doctors' mental ill health.
- Phase 2 will be a realist evaluation of the existing combinations of strategies to reduce doctors' mental ill health in eight purposively selected UK acute NHS trusts in England.
- Phase 3 aims to codevelop an implementation toolkit that all NHS trusts can use to optimise their strategies to reduce doctors' mental ill health.

Throughout the phases, we will draw on the feedback from the project advisory and steering groups along with various other stakeholders (see figure 2, and the 'Involvement of patient and the public' section).

Phase I: typology development

We will use the descriptions of workplace programmes/approaches in the included sources from the CUP1 realist review to develop a typology of intervention.[15] We will conceptualise and describe existing interventions—based on the mechanism they trigger and their theoretical basis. This is in line with Pawson and Tilley's claim that we should not think of interventions as being different because they are called different things, but instead that interventions may be more fruitfully classified by the 'family' they belong to.[33] This typology will enable us to map intervention functions and will assist in informing the purposive sampling of eight acute NHS trusts for phase 2. Previous research and stakeholder engagement in CUP1 noted a wide range of interventions are provided by trusts to support doctors' mental health, but there is no agreed systematic way of categorising them. The absence of agreed terminologies or categories made it hard to compare 'like with like' with any degree of confidence. CUP3 proposes to conceptualise and describe existing interventions—based on the mechanism they trigger and their theoretical basis. While there is likely to be variation between interventions, the CUP1 findings suggested that many interventions are based on a limited number of assumptions, captured in the key recommendations and principles for refining/designing strategies to reduce mental ill health in doctors.[24]

As part of the process, we will also evaluate how well these interventions are described (or not) using the template for intervention description and replication (TIDieR) framework[34] and the Health Service and Delivery Research checklist,[35] in order to encourage future publications to provide the detailed information needed to interpret the findings and/or implement them in other settings. To refine the typology, we will also draw on the programme theory from CUP1[15]; wider methodological literature[34]; and relevant intervention studies/evidence published recently (eg, mental health hubs for hospital staff traumatised by the impact of COVID-19[36]). This will allow us to ensure the wording and components of the typology are relevant for secondary care settings in England.

Phase 2: realist evaluation

We will work with eight acute NHS trusts to develop an explanatory account of how interventions aiming to support doctors challenged by mental ill health are assumed 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.[37]

Refining our initial programme theory

Our initial CUP3 programme theory will be developed by building on the findings from CUP1.[15] We will also use any transferable insights from published CUP2 findings, the results of phase 1 typology development work, additional literature identified through purposive searching and forward citation chasing[38] from CUP1,[15 24] and other relevant literature including insights relevant to doctors' experiences during and associated with interventions related to the COVID-19 pandemic, for example, COVID-19 Doctor Well-being Study.[39]

Data collection

Eight acute NHS trusts in England will be purposively sampled to identify a diverse range of trusts using data from: CQC ratings; NHS Staff Survey; GMC national training survey; local deprivation data and other characteristics, such as size, numbers of staff and location. Eight different trusts will be chosen to provide sufficient variability in the sites to make it more likely that findings would be transferable.

We aim to undertake up to 160 qualitative realist interviews[40] across the 8 trusts—20 interviews per NHS trust, chosen as the optimal number that will give us the greatest insight without redundancy or repetition. We envisage the inclusion of doctors, HR managers, service managers, finance managers, well-being champions, occupational health, psychologists, chaplains, coaches and other relevant staff involved in the design and delivery of support programme (including those who are not trust based).

Phase 1 [Months 1-4] – Jul - Oct 2022	
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] – Nov 2022 – Feb 2024	
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] – Mar - Jun 2024	
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
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 1 Study design for Care Under Pressure 3 (CUP3). NHS, National Health Service.

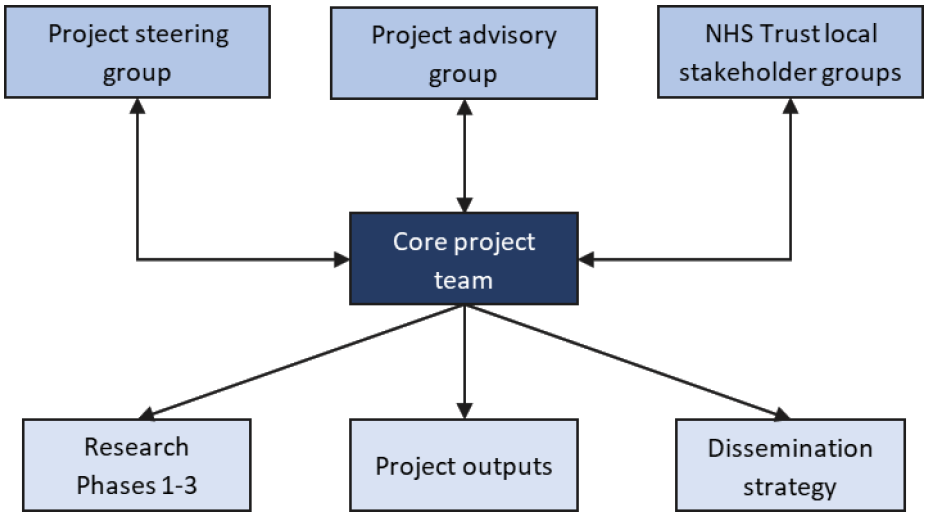

Figure 2 Management and governance of CUP3 and involvement of patients and the public. CUP3, Care Under Pressure 3; NHS, National Health Service.

At the early stages of this project, we also identified areas that were less well represented (such as specialist, associate specialist and specialty (SAS) doctors, Intenraltinal Medical Graduate (IMG) doctors) and targeted recruitment to gain representations from these groups (see online supplemental file).

Participants will be recruited through posters, emails, and (where possible) promotion by key contacts within each trust. They will be given project information so that they can give informed consent before interviews commence.

The interviews will help develop an explanatory account of how different interventions within and across trusts are working, for whom, under what circumstances and why (not), and to understand participants' insights about the different contexts, mechanisms and outcomes that may be important to promote well-being. Where possible, we will complement the interviews with workplace observations (eg, of relevant management meetings) and document analysis.

Data analysis

Data analysis will take place alongside data collection, in line with realist conventions.[40] It will be both inductive (themes created to categorise data identified through the analysis process) and deductive (themes created in advance of data extraction and analysis as informed by the initial programme theory). Underpinning this will be retroductive theorising, which is the process of unearthing causal mechanisms, and a key analytical process in realist methodology.[41] This approach, of concurrent data collection and analysis, means that once we judge that we have reached theoretical saturation for any part of our programme theory we will revise our interview questions so that they focus more on areas of the programme theory that remain less well understood.

Synthesising the evidence and drawing conclusions

A realist logic of analysis builds causal explanations in the form of context-mechanism-outcome configurations (CMOcs) for the programme theory.[42] Interpretive cross-case comparison will be used 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, 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. This process will allow us to explore why some interventions might work well for some doctors and in some contexts but not others. We will then use this in-depth understanding and explanation as a starting point for discussions with the stakeholders at each NHS trust site. We will look at specific interventions, for example, one at each 'level' (individual, organisational, etc), highlight their interdependencies, and develop an explanatory account of whether/how these interventions 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 that can help all trusts to improve their strategies to reduce doctors' mental ill health.

Phase 3: codeveloping an implementation toolkit

Drawing on our refined programme theory, the evidence-based tailored guidance for the eight participating trusts, and our experience gained through phases 1 and 2, we will codevelop an implementation toolkit for all NHS trusts using the Extended Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework to structure discussion and development.[43] We are aware of, and have extensive experience of applying a range of implementation frameworks and theories (The

Consolidated Framework for Implementation Research (CFIR), integrated Promoting Action on Research Implementation in Health Services (i-PARIHS), Normalization Process Theory (NPT)),[44–46] but have chosen to focus on using the Extended RE-AIM framework in view of its explicit coverage of significant (but often overlooked) implementation issues (adaptation, equity, cost, multilevel determinants of sustainability) and its pragmatic inclusion of key questions that can be used directly or tailored to structure discussion in the workshops.

We anticipate this implementation toolkit will provide a framework for NHS trust leads and service managers to work together with doctors and other key stakeholders to assess and improve the effectiveness of their existing strategies, with a focus on their maintenance and sustainability.[43] To create the implementation toolkit, we will hold workshops with our project advisory group and NHS trust local stakeholder groups from phase 2. Contributors will thus comprise those who have an interest and work in the NHS (including patients); doctors and other healthcare professionals. The diversity and richness of our contributors will reflect the complexity of hospital environments, policies and processes. The planning of our workshops will be informed by the outcomes of phases 1 and 2 and our engagement with the project advisory group and local stakeholder groups.

ETHICS

Ethical approval was obtained from the NHS Research Ethics Committee (REC reference number 22/WA/0352) on 22 December 2022. As part of the conditions for our ethics approval, the sites included in our study will remain anonymous.

Patient and public involvement

Patients and the public will be involved throughout the proposed research through memberships to both the project advisory group and steering group (see figure 2). The project advisory group will support all three phases of CUP3, providing content expertise for programme theory refinement. We will also work with site leads at each of the eight selected acute NHS trusts to facilitate recruitment of and engagement with local stakeholders (doctors, managers and patients) during phase 2 (see figure 2). These groups will meet regularly throughout the CUP3 project (via a blend of online and face-to-face meetings, flexible to members' needs and any potential further COVID-19 pandemic scenarios), to discuss the research process, findings, outputs and dissemination. The members include individuals representing different perspectives including doctors from various specialties, doctors who have experienced mental ill health, other healthcare professionals, NHS managers, patients and the public, charities with an interest in mental ill health, and doctor support organisations such as the NHS Practitioner Health Programme. The membership reflects the complexity of the problem we are investigating. Our aim is to incorporate different relevant perspectives and to maximise the dissemination our findings.

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 (phases 1–2).
- Development of feasible and actionable implementation toolkit (phase 3).
- Development and optimisation of dissemination materials (phase 3).
- Dissemination of academic articles and other outputs to different audiences (phase 3).

The advisory group will meet on at least six occasions throughout the project—planned for months 2, 5, 10, 19, 21, 23 of the 24-month project. These meetings are loaded towards the beginning and end of the research period, to maximise input at key development stages. Consideration for additional meetings will be made according to progress and then planned in iteratively to support and maximise the valuable insights that this group can offer to optimise the projects outputs.

The project steering group comprises 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 (see figure 2). The steering group will meet on at least three occasions, in months 4, 12 and 22 of the 24-month project, so as to guarantee input at each phase of the project, with the addition of extra meetings if deemed necessary at the mutual agreement of the group.

We will also form local stakeholders groups at each of the eight acute NHS trusts (eg, doctors, managers, wellbeing leads) during phase 2, to champion our study and facilitate recruitment, and provide feedback as our analysis progresses.

DISSEMINATION, OUTPUTS AND ANTICIPATED IMPACT

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. The project will produce five types of output. We will consult with our project advisory group, and where 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 cocreate an evidence-based doctors' mental health support implementation toolkit aimed at NHS trusts in England.

2. Conventional academic outputs: A report for publication in NIHR journals; at least two manuscripts for publication in a high-impact peer-reviewed; conference presentations (eg, Health Systems Global, Health Services Research UK).
3. Plain English summaries: The research findings will be tailored to different audiences (eg, doctors, patients, health service managers, medical educators, policymakers).
4. More innovative forms: We propose to translate some of our outputs into comics, animations and/or information graphics that might be distributed more widely (eg, for notice boards on wards, inductions, teaching sessions) to help disseminate the implementation toolkit.
5. Media engagement strategy: We anticipate that more traditional forms of dissemination (eg, peer-reviewed publication) will be ineffective in reaching some groups, but other routes (eg, Royal Colleges, UK Foundation Programme Office, Health Services Journal, Pulse, Politics Today, The Conversation, Twitter) may work better for these.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

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