



## **HS&DR Project: 130922 – Optimising the delivery of existing remediation programmes for doctors: A participatory co-design and realist evaluation approach (RESTORE 2)**

### **PROTOCOL: Version 1.0.**

<b>Version control</b>	<b>Date</b>	<b>Author(s)</b>	<b>Rationale</b>
0.1	December 2019	Applicant team	Detailed Project Description submitted with the funding application for Stage 1.
0.2	August 2020	Applicant team	Detailed Project Description submitted with the funding application for Stage 2.
0.3	January 2021	Applicant team	Detailed Project Description updated in response to Funding Committees feedback.
0.4	March 2021	Applicant team	Detailed Project Description updated in response to Funding Committees further feedback.
1.0	July 2021	Investigator Team	Final Detailed Project Description document with updated timeline, anonymised sites and stakeholder group, personal details removed for sharing via the HS&DR website and NIHR funding details added.

## **Title: Optimising the delivery of existing remediation programmes for doctors: A participatory co-design and realist evaluation approach (RESTORE 2)**

### **1. Summary of research (abstract)**

#### Background

The safety of patients is at risk if a doctor is performing below expected standards. Remediation is an intervention used globally to address doctors' underperformance. The successful remediation of doctors has a direct impact on patient safety and the retention of doctors in the workforce. Recognising the importance of this topic, the NIHR HS&DR funded our research team to complete a realist review of the remediation literature (RESTORE 1 – in press). The aim of this review was to understand what kinds of remediation programme work, why, how and for whom. To address this aim we developed a programme theory of how remediation interventions produce their effects. The review found that remediation interventions work when they develop doctors' insight and motivation, and reinforce behaviour change. But, our review also identified significant knowledge gaps. Most studies were from North America: few focused on the UK NHS setting. There was also a lack of detailed high-quality data to effectively test the programme theory and, in particular, the potential contextual impacts on intervention effectiveness. While acknowledging these limitations, we developed a series of recommendations based on our programme theory of how the remediation of doctors produces its effects for those working to deliver remediation programmes.

#### Research Question

How do we optimise the delivery of existing remediation programmes for doctors in the NHS through the use of evidence-based recommendations?

#### Objectives

1. To use a participatory co-design approach to help NHS organisations incorporate evidence-based recommendations to optimise the delivery of existing remediation interventions for doctors
2. To use a realist approach to evaluate and learn from the use and impact of these recommendations on remediation interventions before and after implementation
3. To develop:
  - a. NHS-specific recommendations for the optimisation of remediation programmes
  - b. an 'implementation toolkit' for remediation programme leads in the NHS to improve their remediation programmes based on the NHS-specific recommendations.

#### Methods

This project will use participatory research and realist evaluation approaches to generate primary data across five NHS Sites. The five sites were purposively sampled to involve specific groups of doctors including primary/secondary care, trainees and consultant/GP/SAS doctors. The research will involve three work packages (WPs). WP1 will involve working with each site to optimise the delivery of their existing remediation programme based on the RESTORE 1 'recommendations' using observation and the development of an action plan. WP2 will involve a realist evaluation of the implemented action plan via semi-structured interviews. WP3 will use focus groups to develop an

'implementation toolkit' containing NHS-specific recommendations to improve remediation programmes in the NHS.

#### Timelines for delivery

30 months starting in July 2021.

#### Anticipated impact and dissemination

The study will directly improve the delivery of five remediation programmes in the UK. It will test and refine the programme theory of how remediation works and thereby provide more in-depth 'recommendations' for NHS remediation programmes. The findings will be disseminated via our links with stakeholders, a final report, high-impact peer-reviewed publications, presentations at key stakeholder meetings, and via conferences.

## **2. Background and rationale**

*"When encountering a [doctor] who is not thriving, it is often difficult to figure out what is wrong and how to help. And when confronted with a serious violation of professional ethics or a repeated threat to patient safety, it is equally unclear what to do. ....Unfortunately, problems often become worse, and if uncorrected, result in harm to patients, disruption of the healthcare team, and occasional dismissal..."[pg. xiii]*<sup>1</sup>

Proficient and safe doctors, operating efficiently within teams, are an essential part of the provision of high-quality and safe care for patients.<sup>2</sup> If the performance of a doctor is lacking, patients may be at risk.<sup>2</sup> Doctors can experience performance issues at any stage in their careers for many different reasons. Examples of performance issues include health/wellbeing, personal reasons, the environment of the workplace, or not keeping up-to-date and participating in continuing medical education (CME).<sup>3</sup> Performance concerns are often complex involving multifactorial issues, encompassing knowledge, skills and professional behaviours.<sup>3</sup> To ensure patient safety, it is vital that if there are questions about the performance of a doctor they are identified quickly and, where appropriate, support for the practitioner is provided through remediation.<sup>3</sup>

Remediation is the process by which a doctor's poor performance is "remedied" and the doctor returned to safe practice.<sup>4</sup> Remediation can be formally defined as "an intervention, or suite of interventions, required in response to assessment against threshold standards".<sup>5</sup> Threshold standards are set by regulatory bodies to keep patients safe. What actually constitutes a remedial intervention ranges from informal arrangements to complete some reskilling, through to more formal programmes of remediation and rehabilitation.<sup>6</sup>

It is generally agreed that there are three necessary components of remediation, including the identification of performance deficit, remediation intervention, and reassessment of performance after intervention.<sup>7</sup> Such practices are widely used to varying degrees to remedy poor performance amongst doctors globally. For consultants and General Practitioners (GPs) in the UK remediation is typically carried out by the trust or practice they work in. They may also be referred to the Practitioner Performance Advice Service.<sup>8</sup> This national level NHS body offers advice and guidance to employers on addressing performance concerns and undertakes extensive clinical performance assessments to ascertain the nature of concerns. For trainee doctors, performance support is provided by regional Professional Support Units (PSU's) in Health Education England, Health Education

and Improvement in Wales, and by NHS Education for Scotland. It is estimated that around 2% (around 4,100) of all practising doctors in England will be undergoing remediation at any one time.<sup>9</sup>

The human cost of a failing doctor is difficult to measure and the true societal costs are unknown, but it is estimated that nearly 12,000 patients die in England each year due to preventable medical errors.<sup>10</sup> There is also a corresponding financial cost of failure; the NHS paid out more than £2,227M in medical negligence claims in 2017/18 alone.<sup>10</sup> There are relatively few doctors whom Fitness to Practise panels deem incompetent and clearly need to be stopped from practising. However, there is a continuum of severity in the underperformance of doctors practising in the NHS which is a wider and more complex problem, the solving of which will directly improve the health of the public and NHS patients. Remedying underperformance is both a practical and a financial imperative: doctors are in short supply and expensive to train<sup>11</sup>, and the NHS is facing a workforce crisis, such that NHS England has prioritised this issue in its Long Term Plan.<sup>12</sup> Thus, the proposed research will have a direct effect on delivery of health care services by doctors, improve patient safety, and increase the sustainability of the medical workforce. Hence, the proposed research is consistent with the aim of HS&DR to produce rigorous and relevant evidence to improve the quality, accessibility and organisation of health and social care services.

### Literature review of published evidence

Research on remediation is generally sparse, particularly for practising doctors in the NHS.<sup>13</sup> Three previous literature reviews on remediation within medical education<sup>13-15</sup> all highlight the lack of high-quality studies on the effectiveness of remediation interventions and an urgent need for more research. They were also unable to identify why particular interventions work for some and not others, i.e. the influence of context is neglected. In light of this, we recently completed a realist review of the literature (RESTORE 1) funded by the NIHR HS&DR to understand what kinds of remediation programme work, why, how and for whom.<sup>16, 17 18 19</sup> Our realist review represents the most up to date and current detailed understanding of the remediation literature. We provide details on its findings below. The final report was submitted to the NIHR in January 2020, and is currently in press and awaiting publication in the NIHR Journals Library.

The RESTORE review aimed to identify why, how, in what contexts, for whom and to what extent remediation interventions work for practising doctors, in order to restore patient safety. It followed a detailed protocol based on Pawson's five iterative stages for realist reviews: (1) locating existing theories, (2) searching for evidence, (3) selecting articles, (4) extracting and organising data, and (5) synthesising the evidence and drawing conclusions.

We carried out a formal literature search of databases that index medical and education literature, including: MEDLINE, Embase, PsycINFO, HMIC, CINAHL, ERIC, ASSIA and Dare. These searches were performed in June 2018. We carried out a grey literature search of Google Scholar, OpenGrey, NHS England, North Grey Literature Collection, NICE Evidence, Ethos, Health Systems Evidence and the Trip Database. These searches were performed in June 2019. We searched the bibliographies of included articles and we asked the core research team and stakeholder group to identify relevant literature. We also conducted purposive supplementary searches using Google Scholar to search for particular aspects of the emerging programme theory e.g. insight, motivation, dissonance, psychological safety, self-efficacy, behaviour change.

Our realist analysis developed and refined 29 context-mechanism-outcome configurations (CMOCs). It also developed a programme theory (see Figure 1). Remediation programmes work when they develop practitioner: (a) insight; (b) motivation and; (c) reinforce behaviour change. Key contexts that had an impact on the effectiveness of

remediation interventions were identified at the individual level including: career stage, negative emotions, distrust of remediation processes, fear of remediation consequences, and professional identity development. Important contexts at the level of the setting included workplace environment and the stigma of remediation. Based on our findings we developed a series of recommendations for those working to deliver remediation programmes, on tailoring, implementation and design strategies to improve remediation interventions for doctors (Table 1).

However, our review identified significant knowledge gaps. Only 20 of the 141 studies included in the review were carried out in the UK, the majority were from North America. Thus, few studies focused on the NHS setting. There was also a lack of detailed high-quality data to effectively test the programme theory and, in particular, the potential contextual impacts on intervention effectiveness. While the findings of the realist review are still informative for the NHS, a realist evaluation collecting and using primary data is needed. This will enable us to further develop clearer and highly actionable 'recommendations' specifically for the NHS setting.

Our proposed study therefore aims to fill the knowledge gaps identified by our realist review by addressing the following research question:

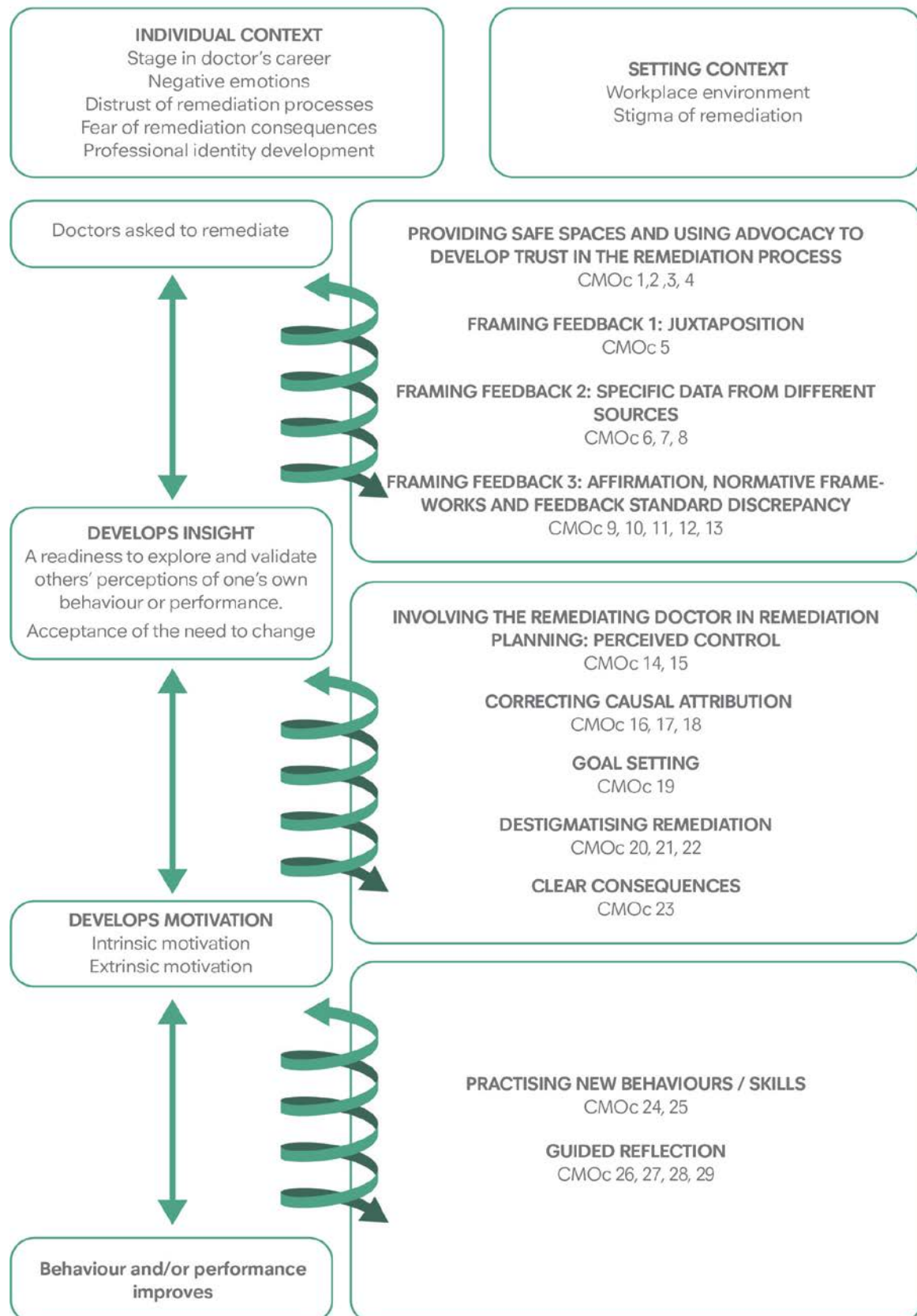
*How do we optimise the delivery of existing remediation programmes for doctors in the NHS through the use of evidence-based 'recommendations'?*

An important aspect of the study is that we will not be creating *new* remediation programmes that the NHS cannot afford to implement or which may take time to introduce and embed. Rather we will work with *existing* programmes to help them sustain and improve what they offer remediating doctors within their contexts and resources.

The study will have a direct impact in shaping remediation programmes by further developing and refining the programme theory developed by our completed realist review. This will be achieved through application to different settings (primary and secondary care, different training levels), and through using primary empirical data to conduct a realist evaluation.

Figure 1: RESTORE Programme Theory

## RESTORE PROGRAMME THEORY OF REMEDIATION



### **3. Aims and objectives**

#### Aim

To optimise the delivery of existing remediation programmes for doctors in the NHS through the use of evidence-based 'recommendations'.

#### Objectives:

1. To use a participatory co-design approach to help NHS organisations incorporate evidence-based recommendations to optimise the delivery of existing remediation interventions for doctors
2. To use a realist approach to evaluate and learn from the use and impact of these 'recommendations' on existing remediation interventions before and after implementation
3. To develop:
  - a. NHS-specific 'recommendations' for the optimisation of remediation programmes
  - b. an 'implementation toolkit' for remediation programme leads in the NHS that helps them to improve their remediation programmes based on the NHS-specific 'recommendations'.

#### Concise statement of proposed research

This project will use participatory research and realist evaluation approaches to generate primary data across five NHS Sites. The five sites were purposively sampled to involve specific groups of doctors including primary care, secondary care, trainees and consultant/GP/SAS doctors. The sites are based in the Southwest of England (n=2), South of England, North of England and nationally. The research will be delivered via three work packages (WP) at each site. WP1 will involve observing and working with site teams to optimise the delivery of their existing remediation programme based on the RESTORE 1 'recommendations', using a participatory co-design approach. WP2 will involve a realist evaluation of the implemented action plan at each site using semi-structured interviews. WP3 will develop a 'implementation toolkit' via focus groups containing NHS-specific recommendations to improve remediation programmes in the NHS. This research will have a direct effect on delivery of health care services by doctors, improve patient safety, and increase the sustainability of the medical workforce.

**Table 1 Findings and recommendations relevant to those working to deliver remediation programmes**

<b><i>RESTORE: Findings and recommendations relevant to those working to deliver remediation programmes</i></b>	
<b><i>Findings</i></b>	<b><i>Recommendations</i></b>
<b>1. Remediation programmes work when they develop insight.</b>	
1.1 Safe spaces for confidential discussion help a remediating doctor become ready to explore issues related to their performance or behaviour.	Remediating doctors should have the opportunity for confidential discussion with someone in a supportive role.
1.2 Juxtaposing a remediating doctor's own values with their actual behaviours help remediating doctors accept the need for change.	Remediation programmes for issues related to conduct should include an opportunity for remediating doctors to reflect on their own professional values and contrast these with the feedback they receive on their own behaviours.
1.3 When a remediating doctor has the support of an advocate, who has no role in summative judgements, they are more likely to develop trust in the remediation process.	Remediating doctors should be supported by someone who has the role of advocate. This individual may be a coach or mentor, and should not have a role in making summative judgements throughout the remediation programme.
1.4 When feedback on performance/behaviour is specific and comes from multiple sources, it is more likely to be validated by a remediating doctor.	Remediating doctors should be provided with specific feedback that details the reasons and examples of underperformance or poor conduct. If the feedback relates to behaviour, it should detail specific events, with a date and time. This feedback should ideally come from more than one source and include feedback from patients whenever possible. Feedback will be needed throughout the remediation process, not just at the beginning. The appropriate feedback to determine progress, and the way that it is delivered, should be ascertained in the remediation planning stage.
1.5 When feedback is framed in a way that is sensitive to a doctor's professional identity, they are less likely to reject that feedback and may accept the need to change performance or behaviour to align with their own professional values.	Feedback may be more effective when in person, and should be guided by someone who has been trained to deliver feedback. The feedback should be framed in such a way that it relates to the professional values of the doctor, is presented in a way that seems manageable, and affirms any identified strengths.
1.6 Remediation is more likely to be successful when assessment is used to explore and identify the full range of possible causes for a "problem".	Multi-modal assessment should be used to explore a full range of potential issues, including behavioural issues, even when the identified problem may appear to relate to knowledge and skills. Assessment should also be used to determine any organisational issues that may contribute to poor performance or behaviour. This will help determine whether the work environment is a contributory factor, and whether this environment will be suitable for undertaking remediation activities. If there are problems with the work environment, then remediation may need to be conducted elsewhere.
1.7 When remediating doctors are facilitated to identify and reflect on the triggers of poor performance or unprofessional behaviour, they are may be able to avoid these reactions in the future.	Remediation programmes should offer the opportunity for the remediating doctor to reflect on the reasons for their referral and to identify the triggers for under-performance/poor conduct.

<b>2. Remediation programmes work when they motivate practitioners to change.</b>	
2.1 If a remediating doctor has input into the design of an individualised remediation programme, they are more likely to have buy-in to the programme and will be more motivated to engage.	Where possible, remediating doctors should collaborate in the design of the individualised remediation plan and help to shape it. The planning stage should include setting scheduled points for assessing progress and determining what kind of feedback will be appropriate for the assessment of this progress.
2.2 When part of the remediation planning process includes setting realistic and achievable goals, the remediating doctor may feel that they are more capable of achieving these goals.	The remediating doctor should collaborate in the process of goal setting, and the goals set should be achievable and measurable.
2.3 When remediating doctors are clear about what happens when targets are achieved or not achieved, they are more likely to choose to engage in the remediation programme.	Remediation programmes should include an individualised plan that specifies the milestones, points for review of progress, and the consequences of achieving or not achieving targets.
2.4 If efforts are made to destigmatise remediation wherever possible, remediating doctors are more likely to engage with the process and be more motivated, because there is less of a threat to their professional identity.	Remediation programmes should seek to destigmatize the process of undergoing remediation and frame it, as far as possible, in terms of positive professional development. If relevant, remediation programmes could consider changing the name from <i>remediation</i> to <i>professional support</i> or similar. Positive framing may also include changing the language around the guidance for remediation, to include terms that indicate support and development.
<b>3. Remediation programmes work when changes to practice are facilitated.</b>	
3.1 When there is an opportunity for remediating doctors to practise new performance or behaviours, these new performances or behaviours are more likely to be integrated into their practice.	Where appropriate, remediation programmes should offer an opportunity for remediating doctors to practise any new skills or behaviours they have developed. This may include rehearsing new behaviours in simulated settings. Where this is not possible, guided reflection can offer an opportunity to reflect on in situ practice.
3.2 When there are scheduled points for guided reflection, remediating doctors have more opportunity to integrate new knowledge and skills and develop further insight.	Remediation programmes should have scheduled points for reviewing progress with the remediating doctor. The remediating doctor should be involved in this process of review and reflections should be guided so that the remediating doctors continues to gain insight into their progress.
3.3 When the remediating doctor has an active role in reflecting on feedback, the feedback is more likely to be accepted and engender a change in performance.	Reflection should be built into the remediation programme and should be guided, but not form part of a final judgement on progress. Reflection may include one-to-one discussion of feedback, or discussions of entries in reflective logs. The purpose of reflection is to have an interesting and meaningful conversation to embed new knowledge and behaviours and engender further insight. Recent medico-legal cases may have placed uncertainty over the confidentiality of reflective logs. The exact legal status of any written reflections should be established in advance.

## 4. Methods

### 4.1 Primary Research: Participatory Research and Realist Evaluation

We propose a three-stage project using participatory research<sup>20</sup> and realist evaluation<sup>21, 22</sup> approaches. Primary data will be generated at five sites to understand how the delivery of remediation programmes for doctors in the NHS can be optimised and to develop NHS-specific 'recommendations'. Essentially we will be using participatory research to refine existing remediation interventions at each site using our RESTORE 1 recommendations. We will then use, a realist evaluation approach to evaluate the refined intervention. The outcomes of this evaluation will then be used to further develop our RESTORE 1 programme theory of how the remediation of doctors produces its effects. This in turn will produce NHS specific recommendations and consider issues relating to the implementation of these recommendations via the toolkit. This research design is underpinned by MRC guidance for the development, evaluation and implementation of complex interventions to improve health.<sup>23</sup>

Participatory research methods are based on a philosophy and ethic of equity. Taking a pragmatic approach, participatory methods enable the researcher to be responsive and bridge the gap between theory, research and practice enabling researchers and stakeholders to drive the research forward and refine the approach to answer the research question.<sup>22, 23</sup> This partnership approach challenges hierarchy within the team and across stakeholders<sup>24</sup> and fits well with realist methods.

Realist approaches assume that few (if any) programmes or interventions work everywhere for everyone: context makes a big difference to programme outcomes.<sup>25</sup> We have adopted a realist approach because it was clear from our realist review (RESTORE 1) that remediation programmes are complex and how well they work (or not) depends on context, who delivers them and how. Furthermore remediation programmes typically do not really pre-exist as an 'off the shelf', ready to go entity. Although some approaches (e.g. training, placements, etc..) are commonly used in remediation, the overall remediation "package is usually (or should be) tailor made for the individual doctor, their issues and their particular circumstances. This makes theory - driven realist approaches particularly apt for this problem area.

Realist research (e.g. realist reviews or realist evaluations) identifies causal processes (mechanisms) for outcomes of interest (intended and unintended). Findings are potentially transferable because in realist research the assumption is that most mechanisms are widely occurring in different settings, situations and/or people, but may not be activated unless the right contexts exist.<sup>26</sup> Using a realist evaluation approach will also enable us focus on the mechanisms (causal processes) for desired and undesired outcomes from remediation. Our realist review has identified important mechanisms that are likely transferable across settings but need to be better understood in the NHS. Our specific focus on the transferable causal mechanisms will enable us to make 'recommendations' for remediation programmes that are relevant and applicable across different settings in the NHS.

### 4.2 Sites and Sampling

The study will involve five remediation programmes in the NHS in the UK (Table 2). The sites were purposively sampled to involve specific groups of doctors including primary care, secondary care, trainees and consultant/GP/SAS doctors. We chose the two sites in the Southwest of England because we had an existing relationship with these sites and were keen to work with us to improve local remediation programmes. These two sites also provide remediation for a broad range of secondary care doctors, thus providing important coverage. We chose a large urban site in the South of England where the population of doctors undergoing remediation is likely to be more diverse (e.g. in terms of ethnic background). The

Practitioner Performance Advice service is a national level NHS body that offers advice and guidance to employers in England, Scotland, Wales and Northern Ireland. Thus, potential participants could be practising anywhere in the UK. The Practitioner Performance Advice service were key stakeholders in the RESTORE 1 study. Finally, we added one additional trust in the North of England to ensure more diversity in terms of the characteristics of the remediating doctors and to add geographic variability. By doing so we have not only added greater diversity but also ensured that we get enough consultant and SAS level doctors as the number of remediating doctors in these groups in the Southwest was low. We are confident that these sites will be sufficiently varied to provide an in-depth understanding of the remediation process for trainee doctors, consultants and SAS doctors in primary and secondary care in the NHS in the North and South of England. Remediation leads were contacted and asked to participate in the study. Letters of support confirming participation in the study were received from each of the four sites during the funding application process.

It is important to note that remediation is a challenging area to research. When we designed this study and reached out to remediation leads, we found that many were reluctant to put doctors undergoing remediation under any further stress by participating in a research study. Understandably many doctors find the remediation process very stressful. This meant that we had to devote considerable time and effort to site selection. The sites we have chosen not only have what we judge to be the diversity needed for this study to be a success, but we have also developed relationships with them and they had been very proactive in their interest and participation in the study to date. This preparatory work will be important in ensuring the success of this study.

**Table 2: Study sites**

<b>Location of remediation programme</b>	<b>Participants</b>	<b>Primary/Secondary Care</b>
Southwest of England	Trainees	Primary and Secondary Care
South of England	Trainees	Primary and Secondary Care
National Level Service	Consultants, GP's and SAS doctors	Primary and Secondary Care
Southwest of England	Consultants and SAS doctors	Secondary Care
North of England	Consultants, & SAS Doctors	Secondary Care

### 4.3 Data Collection

#### **Work package 1: Optimising delivery of remediation programmes based on the RESTORE 1 'recommendations' using a participatory co-design approach (Months 4-13)**

The output of work package 1 (WP1) will be an agreed action plan of the changes needed to optimise the delivery of the existing remediation programme at each site. Due to the unique nature of how remediation programmes are designed and operated in different NHS settings, a one-size fits all approach would not be feasible. Thus, the agreed action plan and outcome measures utilised will be tailored to each individual site using participatory research.

Participatory research (PR) involves the co-construction of research through partnerships between researchers and people affected by and/or responsible for action on the issues under study (e.g. remediating doctors, remediation programme leads – the 'site team').<sup>20</sup> Working in partnership with each site team, the research team will gain an understanding of how their existing remediation programme works and what a successful programme would look like for them. It is important for realist evaluation that various proximal outcomes are considered in developing an understanding of how the programme is working. Therefore, definitions of success will be agreed collaboratively in the team meetings.

The research team will start by discussing the 'recommendations' developed from RESTORE 1 with the site team to see which are most appropriate for their respective contexts prior to making any changes they judge to be needed. This would be achieved through a series of meetings (n= 2-3) between NB, the Research Fellow (RF) and the site team, carrying out observations (n=3) of the remediation programme, and how teams and systems operate on the ground and taking field notes of the same. A participatory ethnographic approach<sup>27</sup> will guide the observations. Ethnography seeks to understand the culture of a particular setting or environment. It is inherently a co-constructed process of research practice that emerges and evolves over a period of sustained co-inquiry, rather than inquiry driven by the researcher's interests. Observation and field notes are corner stones of the approach, which allow the development of relationships with research participants providing an insight into the context, with a focus on the culture and social interaction of the subject of study. Ethnography is particularly valuable in understanding the influence of social and cultural norms on the effectiveness of health interventions, and understanding how complex interventions work.<sup>28</sup> The RF will carry out the observations of the remediation programmes at each site and will take field notes.

These ethnographic activities will enable the coproduction of a site-specific action plan and a list of agreed outcome measures to judge the success of their remediation programme. Using this participatory approach means it is not possible to provide a list of the outcome measures at this point in time. Instead, this will emerge when we understand the needs of each site. However, we do plan to use some common outcome measures across all of the sites. In order to identify these outcome measures we will encourage and facilitate debate and agreement across the sites. The outcome measures may be quantitative e.g. numbers of remediating doctors returning to work, programme engagement levels, assessments of performance, number of complaints, 360 degree feedback, insight/reflection scales. They may be qualitative e.g., faculty and doctors' perceptions of the intervention, or of changed attitudes towards remediation. We will collect data on agreed outcome measures prior to the implementation of the changes outlined in the action plan by the site team, as baseline data against which to compare data after the implemented changes to demonstrate their impact. Each site team will then be supported by the research team to implement the action plan and outcome monitoring process drawing on established implementation guidelines.<sup>29</sup> Lay members of our stakeholder group will be encouraged to feedback and contribute to the action plans.

## **Work package 2: Evaluation of implemented action plan and outcome monitoring process (Months 18-24)**

The output of WP2 is refined NHS-specific 'recommendations' for the optimisation of NHS remediation programmes. Between 6 and 12 months after the implementation of the recommendations, we will use a realist evaluation approach<sup>22, 26</sup> to understand which recommendations have enabled change for which outcome measure, for whom, to what extent, in what contexts, how and why. This timeframe should allow adequate time for the action plan to be implemented and become embedded in remediation practice. Realist evaluation is a methodological approach that uses primary data to address these questions. Realist evaluations can be undertaken with qualitative and/or quantitative data.<sup>25</sup> The primary data we collect will enable us to confirm, refute or refine parts of our RESTORE 1 programme theory (see Figure 1). We will use the refined CMOc's in our improved programme theory to update our original 'recommendations' on how remediation providers can optimise their programmes specifically in NHS settings.

A summary of data collection activities at each site is presented in Table 3. The evaluation will involve semi-structured interviews<sup>30, 31</sup> with 10-15 stakeholders (e.g. programme leads, remediating doctors, medical directors acting as remediating doctors line managers, educational supervisors, Human Resources) at each of the five sites (50-75 interviews in total). This is likely to provide enough data for theoretical saturation. Sampling for realist interviews is theory based, i.e. respondents are selected because they are in a position to cast light on a hypothesis or a particular aspect of the programme theory.<sup>32</sup> Because the unit of analysis is not the person but the events and processes around them (i.e. the remediation processes), every respondent can uncover a collection of micro events and processes, each of which can be drawn upon in our analyses to test theories. This means that a relatively small number of participants with detailed knowledge of the programme can be interviewed multiple times to reasonably confirm, refute or refine the initial RESTORE 1 programme theory.<sup>32</sup>

Face-to-face interviews will be carried out by the study RF in a private space convenient to the interviewee. If necessary (e.g. Covid restrictions, or for participants convenience), interviews may also be carried out over the telephone or by video-call (Skype, Zoom, Microsoft Teams). A schedule will be developed and piloted, evolving as the programme theory is refined.<sup>32</sup> Interviews will be audio recorded and transcribed verbatim. Transcription will be carried out by professional transcribers who specialise in medical interviews.

We have deliberately chosen to use a realist evaluation approach to address the issue of the generalisability/transferability of any learning from the project. Using such an approach enables us to: i) not only understand the influence of contexts on the important outcomes from the remediation process; (ii) but also, by focussing on the behaviour of the mechanisms within different contexts, provide knowledge that is transferable. As part of the realist analysis we will endeavour to explore whether the characteristics of doctors that have undergone remediation could function as important contexts that impact on how the remediation of doctors produces its effects. These characteristics will include gender, ethnicity, age, specialty.

**Table 3: Summary of data collection at each site**

Location of remediation programme	Observations of remediation programmes (WP1)	Data on agreed outcome measures (WP1)	No. of remediating doctors interviewed (WP2)	No. of remediation staff interviewed (WP2)	No of Focus Groups (WP3)
Southwest of England	1-3	Site specific	6	9	2
South of England	1-3	Site specific	6	9	2
National Level Service	1-3	Site specific	6	9	2
Southwest of England	1-3	Site specific	6	9	2
North of England	1-3	Site specific	6	9	2
Totals	5-15		30	45	10

### Data analysis of observation, interview and quantitative data

All field notes from the observations and interview transcripts will be entered into NVivo 12 computer-aided qualitative data analysis software for analysis. Where possible and relevant other variables (e.g. the characteristics of the doctors and the settings they work in) will also be entered into NVivo.

Data will be analysed using the same realist logic of analysis that we used in RESTORE 1.<sup>18</sup> A realist logic of analysis is a way of interrogating theory with data and of using theory to understand patterns in data to further refine the programme theory. A realist analysis of data follows a generative explanation for causation that is, an outcome (O) of interest was generated by relevant mechanism(s) (M) being triggered in context (C).<sup>33</sup> Data analysis is iterative over the course of the evaluation, with earlier stages of analysis being used to refine programme theory and/or refine evaluation design for subsequent stages. Following each data collection period, the analysis will involve reading and rereading the transcripts and field notes before moving on to coding. In this sense the data is purposely mined for information that would help us refine/challenge/develop the CMOcs that we found in our realist review from RESTORE 1. Where indicated by our interpretations of the data we will develop and refine new CMOcs based on the primary data collected in this study. In reality this process is not linear, and will involve much iteration, discussion and deliberation between and across phases.

Throughout the analysis we will move iteratively between the analysis of examples, refinement of programme theory, and further iterative primary data collection to test specific parts of the programme theory.<sup>18</sup> As mechanisms are often hidden or not articulated very well we will use retroductive reasoning to infer and elaborate on the mechanisms. Retroductive analyses are analytical processes that seek to identify the hidden causal processes that lie beneath identified patterns or changes in those patterns.<sup>34</sup> Thus our approach involved repeatedly going from data to theory, to refine explanations about the occurrence of certain behaviours. We will endeavour to construct these explanations at a level of abstraction that would encompass a range of phenomena or patterns of behaviour.

We will try to identify relationships between contexts, mechanisms and outcomes from within and across different data sources (e.g. inferred mechanisms from one interview/observation could help explain the way contexts influenced outcomes in another interview). We will use these analytic processes:

- a) Juxtaposition of sources of evidence e.g. where evidence about behaviour change in one source allows insights into evidence about outcomes in another source.
- b) Reconciling of sources of evidence – where results differ in similar situations, these were further examined to find explanations for these differences.
- c) Consolidation of sources of evidence – where different outcomes occur in similar contexts, a reason can be developed as to how and why these outcomes happen differently.

In terms of the analysis of quantitative data collected in WP1 based on the outcome measures chosen by the individual sites, the sample will be too small to carry out any statistical analysis however we can use descriptive statistics (e.g. frequencies) to look for patterns. We can also use our interpretations of any changes in the relevant quantitative data to confirm, refute or refine our CMOcs.

The refined programme theory and our findings will form the basis of our NHS specific 'recommendations'. We will produce a table similar to that used in RESTORE 1 (Table 1 pg.7) using similar methods.<sup>18</sup> This table was highly commended by the report editor for its clarity and applicability. The table will detail our key findings on how the remediation of doctors produces its effect in NHS settings and along with a series of recommendations on how to tailor and implement remediation interventions relating to each specific finding. See Table 1 pg.7.

### **Work package 3: Development of an 'implementation toolkit' containing NHS-specific recommendations to improve remediation programmes in the NHS (Months 18-24)**

WP3 will involve the development of an 'implementation toolkit'<sup>35</sup> for remediation providers on how to apply the NHS-specific 'recommendations' developed in WP2 to improve their existing programmes. We will draw on behaviour change research by Michie to underpin the design of the toolkit.<sup>36, 37</sup> The behaviour change wheel (BCW) outlines nine intervention functions aimed at addressing deficits in a particular 'behaviour system'. Our findings from WP2 will enable us to understand what behavioural changes are needed from remediation providers to optimise the delivery of their service. We will then use these findings to select the appropriate blend of interventions suggested by the BCW. The toolkit will include detailed information on how to use the 'recommendations' in different contexts and populations (i.e. different remediating doctor groups). Such a 'tool kit' is needed as remediation programmes are not only delivered differently in different locations, but also because trying to 'force' each programme to make one-size-fits-all changes is not only unlikely to work but would also be unacceptable to local remediation services. Our 'tool kit' will enable NHS remediation services to deliver better services themselves.

Using a participatory research approach<sup>20</sup> the 'toolkit' will be developed through a series of focus groups with each of the five site teams (n=2 per site, 10 in total). Approximately 6-8 stakeholders will participate in the focus groups at each site e.g. the remediation leads, remediating doctors, medical directors, educational supervisors, patients and the public. The first focus group will involve an in-depth discussion of the implementation of each recommendation in detail. This will include:

- Practical advice learned from applying the recommendations at their site
- Common contextual factors and populations that affect the success of each recommendation including examples.

The focus groups will be held in a private room at each site and will be led by the RF. The focus groups will be digitally audio-recorded and transcribed verbatim by a professional transcriber bound by a confidentiality agreement. Participants will be anonymised prior to

transcription and will be referred to by a reference number. The transcripts will be uploaded into NVivo 12 and thematically analysed. The data generated at each site on each individual recommendation will be compiled and analysed by the research team. This analysis will inform the contents of the 'toolkit'. A draft of the 'toolkit' document will then be developed by the research team and the stakeholder group and shared with each site.

Each site will review the 'toolkit' and then discuss and provide feedback on its usability via a second focus group. Details on how the 'toolkits' will be disseminated are outlined in the following section.

## **5. Dissemination, outputs and anticipated impact**

There will be one substantial output from the study, namely an NHS-specific 'implementation toolkit' that contains:

- a) a refined programme theory of how remediation programmes in the NHS produce their effects
- b) refined 'recommendations' for optimising remediation programmes
- c) practical advice for NHS remediation programme leads on using each 'recommendation' to self-improve their programmes
- d) practical guidance for each programme lead to review the success of their programme, encompassing qualitative and quantitative indicators.

Our dissemination strategy will build on the participatory approach of our research, with input from the site teams and PPI representatives to ensure that the project outputs will be used by the NHS. We will also leverage our pre-existing relationships with stakeholders from RESTORE 1. Our stakeholders include members from key organisations that are well placed to disseminate and implement our project output (see section 4.8 below for membership of the stakeholder group). Examples of our audiences eagerly awaiting the findings of this study include the Practitioner Performance Advice Service. As mentioned in previous sections, this service operates across England, Scotland, Wales and Northern Ireland. Other audiences include the leads for the Professional Support Units throughout the UK as well as NHS organisations/providers who implement remediation programmes.

At our Month 18 stakeholder group meeting, we will consult with them on the formats and content that would be most suited to their colleagues. We anticipate at present (pending feedback and advice from our stakeholders) that the findings will be disseminated via:

- a) publication in peer-reviewed journals
- b) user-friendly summaries of the findings and recommendations tailored to the needs of interested audiences including patients
- c) relevant conferences e.g. HSR UK
- d) PSU meetings (the leads for the different PSUs across the UK meet regularly at the Conference of Postgraduate Medical Deans (CoPMED) <https://www.copmed.org.uk/>; we plan on presenting the findings of the study at one of these meetings and distributing the 'toolkit' to the PSU leads)
- e) RO Network Meetings including both regional and national events <https://www.england.nhs.uk/medical-revalidation/ro/train-net/>. These meetings are attended by Medical Directors (MDs)/Responsible Officers (ROs) of primary and secondary care trusts across the UK; we plan on presenting the findings of the study these meetings and distributing the 'toolkit' to the MD's/ RO's.
- f) providing the 'toolkit' in an open access format online so that it is available for use by any remediation programme in the NHS.

The expected impacts of this study are three-fold:

Firstly, it will directly improve the delivery of five remediation programmes in the UK. Secondly it will test and refine the programme theory of how remediation works which will thereby provide more in-depth 'recommendations' for remediation programmes across the NHS. We will then use this programme theory to develop a 'toolkit'. This will directly serve as a framework for any NHS remediation programme provider to optimise the delivery of their existing and future programmes. As such, it establishes the evidence base for remediation programmes in the NHS that is currently lacking. Thirdly, this study will result in tangibly improved remediation practice, with a network of experts (including the Practitioner Performance Advice Service) well-positioned to further advance knowledge and application of successful medical remediation.

Given the practical and moral imperatives of improving remediation in a way that will sustain patient safety, the outcomes of this project will be central to the patient safety agenda and the NHS's objective of "creating the safest, highest quality health and care service".<sup>38</sup>

## 6. Project timetable

The proposed project timetable is outlined in table 4 on pg. 18.

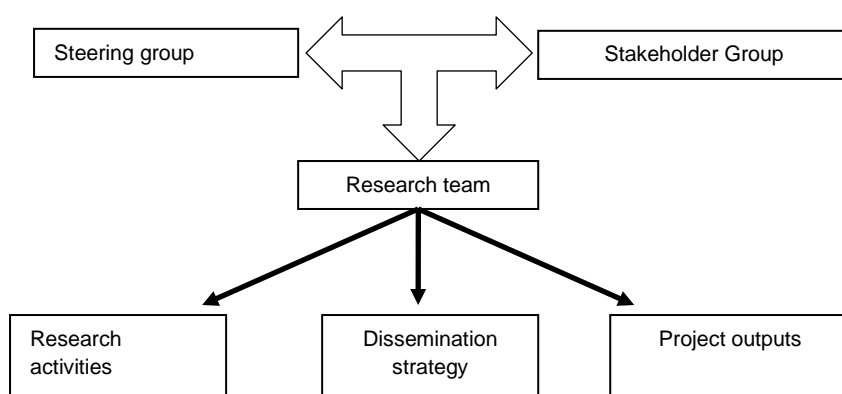
## 7. Project management

The project will be managed via three groups:

1. the research team
2. the steering group
3. the stakeholder group.

The projects organisational structure is depicted in Figure 2.

**Figure 2: Project's organisational structure**



### Research Team

The day-to-day running of the project will be managed by the research team. The research team will consist of all co-applicants, the Research Fellow (RF) and Research Assistant (RA) employed to carry out the research. This team will plan and monitor day to day progress, ensure ongoing communication among team members, study quality and timeliness of outputs, and manage day-to-day risks and issues. The research team will be responsible for undertaking the research, producing the project outputs and dissemination.

We will use online software as needed to enable us to conduct high-quality remote interaction and file sharing. The research team will meet bi-monthly. In between these meetings the research team will be in regular contact as needed (e.g. via email, telephone and video-call). The meetings will be chaired by NB who will also line manage the RF and RA. This infrastructure will support (but not replace) regular meetings between different members of the research team, as needed, to execute the study, plan data collection, conduct analyses, discuss emerging findings and prepare outputs.

#### Steering Group

The project will also involve a steering group to provide project oversight, monitor progress against milestones and oversee research governance and financial management. We will hold six steering group meetings throughout the study as set out in the project timetable above. The group will also provide advice, promote the project, communicate with stakeholders and help maximise dissemination and impact of findings.

#### Stakeholder Group

The stakeholder group will consist of two groups of participants i.e. lay members as well as a variety of key professional stakeholders in the remediation process e.g. remediating doctors, those delivering remediation programmes, policy makers. The stakeholder group will: help us to sense check emerging findings; provide additional feedback and advice that will enable us to optimise our outputs and dissemination plans and; produce feasible and practical recommendations for relevant wider stakeholders. The stakeholder group will also have members from key organisations having people/bodies who will use the end product, or be in a position to promote it's use so they will be involved in the study throughout. Four stakeholder meetings will be held throughout the study.

**Table 4: Plan of investigation and timetable (gannt chart)**

Task	Year 1												Year 2												Year 3					
Month	Jul '21	Aug '21	Sept '21	Oct '21	Nov '21	Dec '21	Jan '22	Feb '22	Mar '22	Apr '22	May '22	Jun '22	Jul '22	Aug '22	Sept '22	Oct '22	Nov '22	Dec '22	Jan '23	Feb '23	Mar '23	Apr '23	May '23	June '23	July '23	Aug '23	Sept '24	Oct '23	Nov '23	Dec '23
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
<b>Project Management</b>																														
Secure ethics approval																														
Research Team Meetings																														
Steering Group meetings																														
Stakeholder (incl PPI) meetings																														
<b>Data Collection</b>																														
WP1																														
Site 1 observations & action plan dev																														
Site 2 Observations & action plan dev																														
Site 3 Observations & action plan dev																														
Site 4 Observations & action plan dev																														
Site 5 Observations & action plan dev																														

Task	Year 1												Year 2												Year 3					
Month	Jul '21	Aug '21	Sept '21	Oct '21	Nov '21	Dec '21	Jan '22	Feb '22	Mar '22	Apr '22	May '22	Jun '22	Jul '22	Aug '22	Sept '22	Oct '22	Nov '22	Dec '22	Jan '23	Feb '23	Mar '22	Apr '23	May '23	June '23	July '23	Aug '23	Sept '24	Oct '23	Nov '23	Dec '23
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Data Collection																														
WP2																														
Prepare materials for evaluation																														
Site 1 Interviews																														
Site 2 Interviews																														
Site 3 Interviews																														
Site 4 Interviews																														
Site 5 Interviews																														
WP3																														
5 sites focus groups																														
Data Analysis																														
Analysis of obs, interviews, focus groups etc..																														
Dissemination Activities																														
Preparation of outputs, academic papers, report and dissemination																														

## **8. Project/Research expertise**

Chief investigator:

Nicola Brennan, Chief Investigator on RESTORE 1, content expertise in remediation, realist and qualitative methodologist, providing overall project coordination, responsibility for delivery and timescales, line management of RF; will oversee data collection and analysis.

Co-applicants:

Dr Tristan Price is an experienced qualitative medical education researcher. Tristan was the Research Fellow on the RESTORE 1 study, and thus will provide content knowledge of the remediation literature. Tristan will support WP's 1-3. Tristan will have a leading role in the recruitment of remediating doctors and will also will lead PPI activities. Tristan will attend project meetings and review outputs.

Dr Geoff Wong is an experienced realist methodologist and GP. Geoff will provide realist methodological guidance and support to all stages of the project, attend project meetings and review outputs. Geoff's expertise will be particularly important in WP2. Geoff will provide mentorship to the C.I. as Geoff has been C.I. on a number of NIHR grants.

Prof Tom Gale is an experienced quantitative medical education researcher and anaesthetist. Tom will provide topic guidance, attend project meetings and review outputs. As a secondary care consultant at University Hospitals Plymouth NHS Trust with significant experience in training, educational supervision and remediation, Tom will liaise with stakeholders at study sites to identify remediation interventions and outcome measures. Tom will also provide mentorship to the C.I. particularly in leadership skills, and research and governance at the University of Plymouth.

Prof Jen Cleland is an experienced medical education researcher particularly in remediation of doctors. Jen will provide topic guidance, contribute to qualitative components of WP2, attend project meetings, contribute to the writing of the final report and review outputs. Jen will also provide mentorship to the C.I. on managing primary research studies.

Dr Helen Lloyd is an experienced participatory and qualitative researcher and will provide methodological guidance, attend project meetings and review outputs. Helen's expertise will be particularly drawn on for WP1 of the study which involves participatory research.

Dr Lyndsey Withers is an experienced PPI participant and will provide PPI input through attending project meetings and reviewing outputs.

Researchers:

Post-doctoral Research Fellow (Grade 7) will manage the project day-to-day, carry out data collection and analysis.

Research Assistant (Grade 6) will support will carry out data collection and analysis and provide admin support e.g. arrange meetings.

The roles of the C.I. and the research team are summarised in Table 6

**Table 6 Roles of C.I. and Co-applicants**

	Content Expertise	Methodological Expertise	PPI	WP1	WP2	WP3	Review Outputs	Attend team meetings	Mentor C.I.
Nicola Brennan	✓	Realist methods		✓	✓	✓	✓	✓	
Tristan Price	✓	Realist methods	✓	✓	✓	✓	✓	✓	
Geoff Wong	✓	Realist methods			✓	✓	✓	✓	✓
Thomas Gale	✓	Quantitative methods		✓		✓	✓	✓	✓
Jen Cleland	✓	Qualitative methods			✓	✓	✓	✓	
Lyndsey Withers	✓		✓	✓		✓	✓	✓	
Helen Lloyd		Participatory/ qualitative methods	✓	✓		✓	✓	✓	

## 9. Funding acknowledgement

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