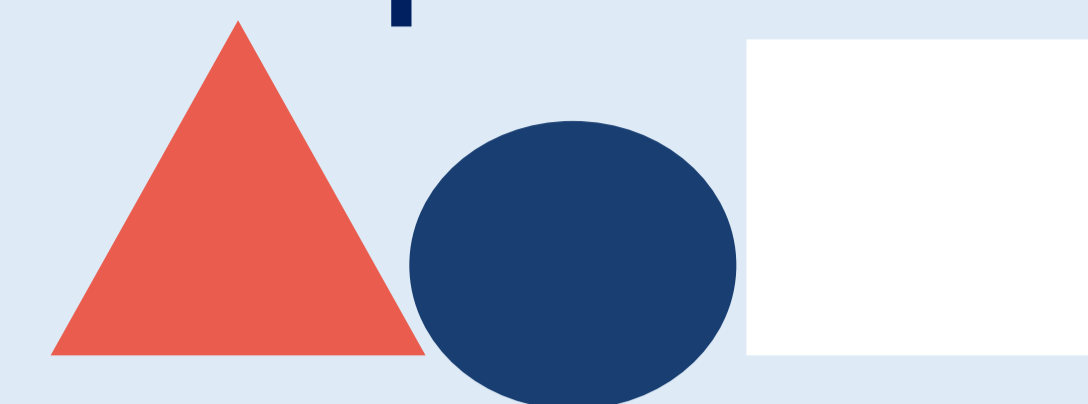


# Supporting Hospital And Paramedic Employees (SHAPE) with Cognitive and Behavioural Coaching for PTSD and Depression

Jasmine T Laing, DPhil Candidate, Supervised by Professor Jennifer Wild and Professor Cathy Creswell.  
University of Oxford



## Main Objectives

By the end of this study, we aim to achieve:

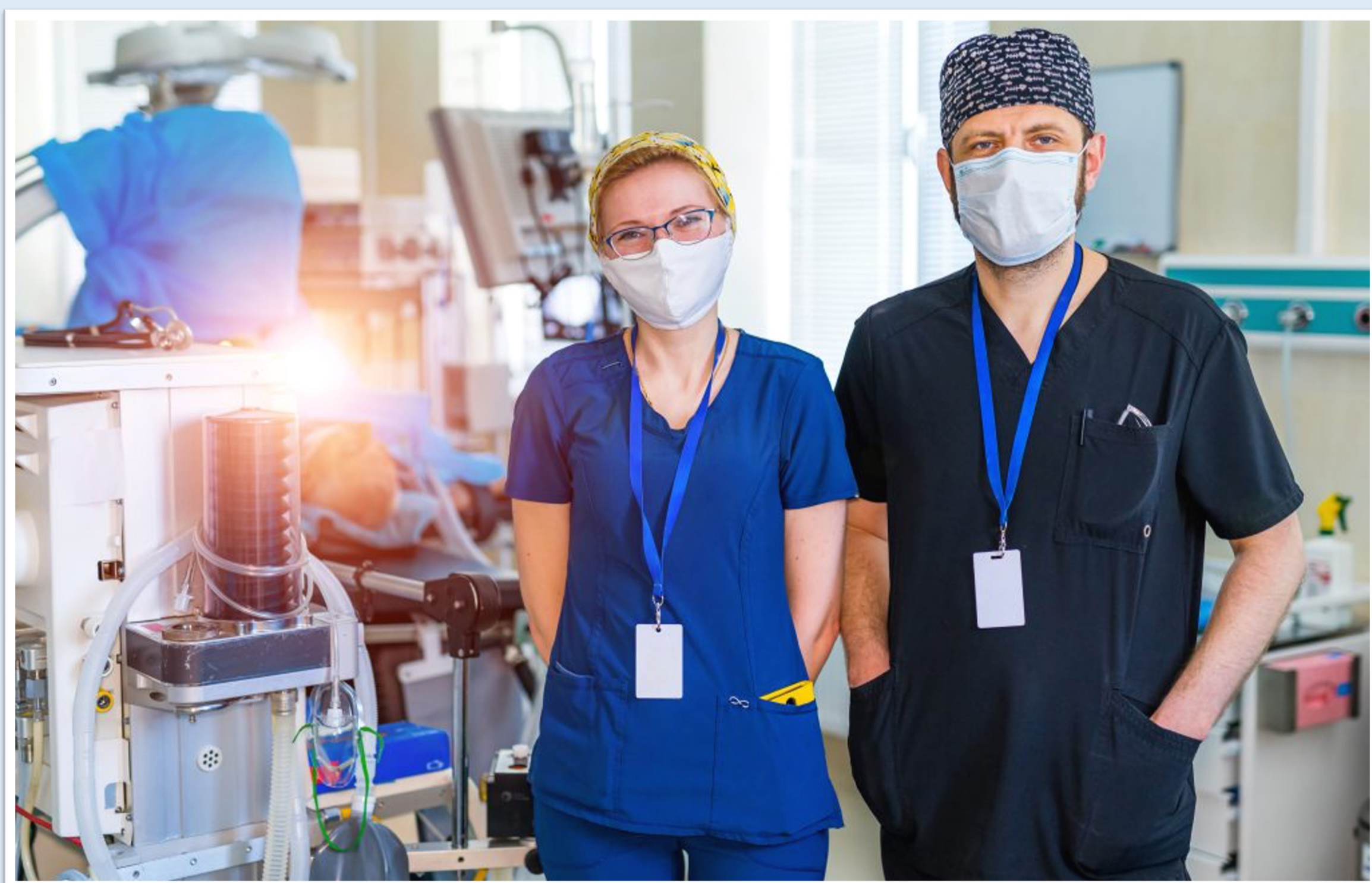
1. A rigorous evaluation of the SHAPE recovery intervention
2. Evidence to inform NICE guidelines on preventing the development and persistence of posttraumatic stress disorder and major depressive disorder
3. A deeper understanding of SHAPE's efficacy across different populations using patient and public involvement
4. A potentially scalable and effective model of outreach for healthcare staff
5. Translatable findings for healthcare workers regularly exposed to trauma

## Introduction

- Healthcare workers have an increased risk of developing posttraumatic stress disorder (PTSD) and major depression due to trauma exposure in occupational and personal settings.<sup>1</sup>
- The COVID-19 pandemic has exacerbated rates of PTSD and major depression in healthcare workers due to factors like burnout, poor working conditions, higher exposure to witnessing death, and fear of becoming infected and infecting others with the virus.<sup>2</sup>
- Quality of patient care has been linked to the mental health status of healthcare workers adding to the severity of this issue.<sup>3</sup>
- There is a lack of tailored, evidence-based, psychological interventions to support healthcare workers to manage symptoms of PTSD and depression.<sup>4</sup>
- Empirically validated interventions are therefore needed to support healthcare workers to protect their mental health and quality of life, as well as their patients.<sup>5</sup>
- Supporting Hospital And Paramedic Employees (SHAPE) is a short, semi-structured, transdiagnostic intervention that is based on empirical evidence to reduce symptoms of PTSD and major depression in healthcare workers.
- A pilot study of 103 healthcare workers demonstrated that the SHAPE recovery intervention achieved clinically significant change in symptoms of PTSD and major depression within six weeks of wellbeing coaching, compared to little change achieved during a three-week monitoring phase (see Figure 1).
- A randomised controlled trial (RCT) is now needed to evaluate the efficacy of the SHAPE recovery intervention.
- Importantly, we will investigate the processes which underlie the effects of the intervention (mediation) as well as for whom the intervention works less well (moderators) so that we can make the intervention more precise and effective.

## Patient & Public Involvement

- In line with the goals of the NIHR ARC Oxford and Thames Valley, we aim to involve key stakeholders throughout the design, implementation and evaluation stages of this RCT.
- The UK healthcare workforce is highly diverse, so ensuring interventions like SHAPE can benefit people from different backgrounds is essential.
- We therefore aim to involve diverse healthcare workers throughout the entire research programme from design to dissemination.
- We have been in contact with Dr Rosena Allin-Khan, MP and accident and emergency doctor, who acknowledges the benefits of SHAPE and told us '...there is certainly a need for improved mental health support for frontline workers.' She asked to be kept informed of the progress of SHAPE so that she may help further on the down the line (e.g., dissemination)
- We plan to work with key stakeholders from the Filipino Nurses' Association via a series of online consultations to better understand the experiences and needs of this population.



## Methodology

### Participants

- We aim to recruit 128 healthcare workers across six different Trusts in the United Kingdom to reach required power.
- Inclusion criteria include working as a healthcare worker, being over 18 years of age, and having low mood or PTSD as a primary presenting problem.
- Participants will also need to consent to being randomised.

### Groups

- Intervention Group:** Participants randomly allocated to this group will receive six sessions of SHAPE coaching over an eight-week period.
- Control/Standard Practice Group:** Participants randomly assigned to this group will undergo an eight-week wait period with limited contact from the research team. Participants will then be reassessed and will have the choice to partake in the SHAPE recovery intervention if they meet criteria for either PTSD or major depression.

### Measuring PTSD and Depression

- We will use the PTSD Checklist for DSM-5 (PCL-5) and the Patient Health Questionnaire 9 (PHQ-9) to screen for and track symptoms of PTSD and major depression respectively at baseline, once a week during the intervention, at post-intervention and at six months post-intervention.
- Cut-offs – Informed from the data in our pilot study, we have set our clinical cut-offs for PTSD and major depression to be 20 on the PCL-5 and 10 on the PHQ-9 respectively.
- In addition, we will use the Structured Clinical Interview for DSM-5 (SCID-5), to diagnose PTSD and major depression in participants at baseline, pre-intervention (for participants assigned to the control group), post intervention, and at six months post-intervention for higher reliability in our assessments.

### Measuring individual differences and process measures in SHAPE

- We will conduct moderation and mediation analyses to measure the different factors that influence how individuals respond to SHAPE, and the specific processes that underlie the effects of the SHAPE intervention. For the moderation analysis, variables of interest include age, gender, childhood adversity and social support, for example. For the mediation analysis, variables of interest include responses to intrusions, posttraumatic cognitions and emotion regulation.

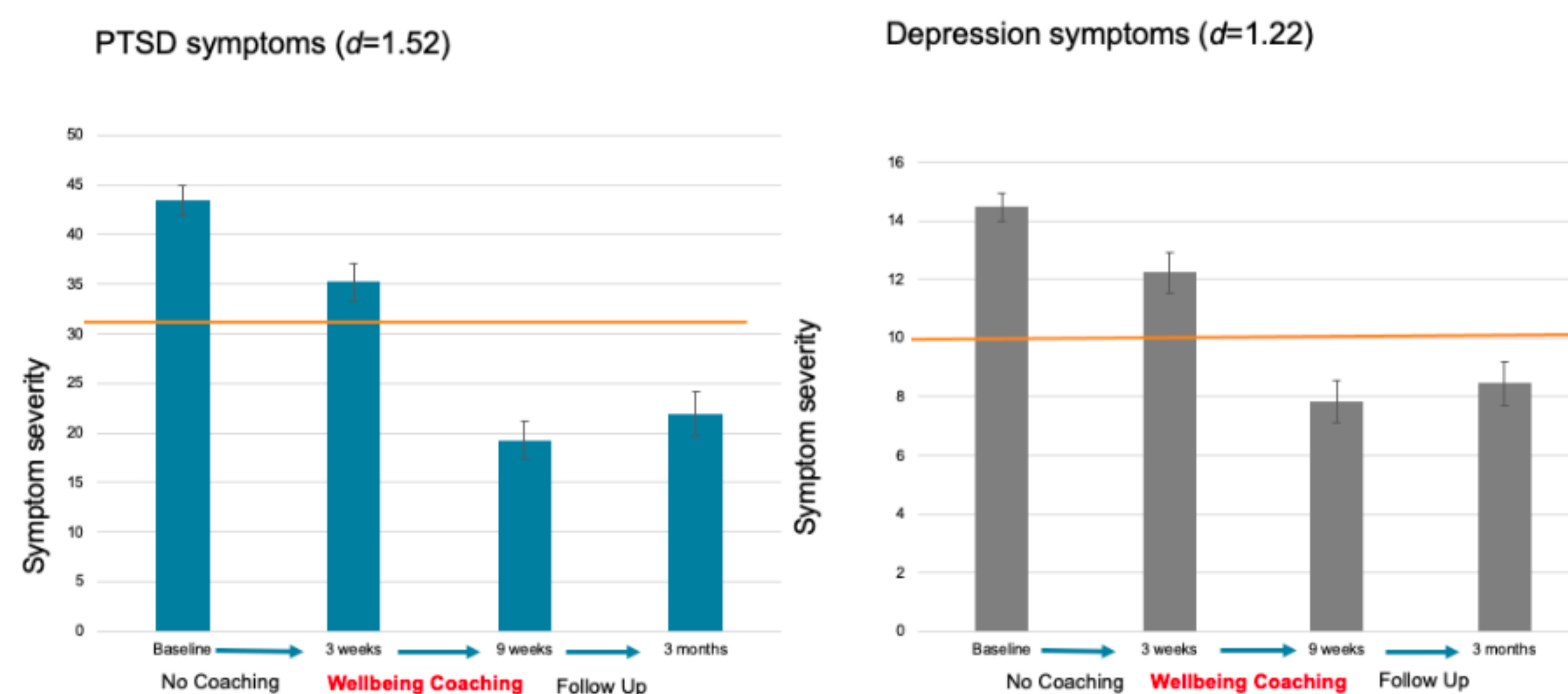
### Timeline for the RCT

- Recruitment will begin in December 2022 and will end in April 2024.
- The SHAPE intervention will begin in January 2023 and is planned to finish by August 2024.

## SHAPE Recovery Intervention

- SHAPE is a short, semi-structured, transdiagnostic intervention that is based on empirical research.
- Participants who take part in the SHAPE recovery intervention are assigned to a wellbeing coach and have six wellbeing calls over the course of eight weeks (one call per week).
- Drawing on our systematic research with healthcare workers, which first identified predictors of PTSD and depression<sup>6</sup>, SHAPE aims to modify cognitive and behavioural processes that predict and maintain PTSD and major depression.
- Wellbeing calls are active, experiential, evidence-based and are informed by the weekly questionnaires (PCL-5 and PHQ-9) and guided by the coach. Wellbeing calls last between 20-40 minutes.
- SHAPE utilises seven evidence-based core tools that coaches can choose to work on with their participant depending on the participant's presenting symptoms. In addition, each tool comes with an accompanying online module that participants can choose to work on in their own time in between sessions.

Figure 1  
Preliminary results from pilot study of SHAPE (Wild et al., 2022)



Note. The orange line shows the clinical cut-off for PTSD and depression.

## Conclusion

- A randomised controlled trial is needed to rigorously evaluate the efficacy of SHAPE prior to wider dissemination.
- Our analyses will help to determine for whom the intervention works and for whom it works less well (moderation). We will also investigate the processes which underlie the effects of the intervention (mediation). These results will help us to make SHAPE more precise and effective.
- Working with key stakeholders will allow us to further refine and improve SHAPE to ensure SHAPE can help as many different groups of healthcare workers as possible.
- This research is possible thanks to the support of the NIHR ARC Oxford and Thames Valley. We hope for better mental health outcomes in healthcare workers across the UK after the evaluation and dissemination of SHAPE.

Contact: Jasmine T Laing, Department of Experimental Psychology, Email – [jasmine.laing@psy.ox.ac.uk](mailto:jasmine.laing@psy.ox.ac.uk)

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