# Survive and Thrive. Exploring the wellbeing of doctors in a post Covid 19 era: a Core Outcome Set to measure wellbeing.

ERGO Reference number: 55747

Date: 07/04/2020

Version 0.5

Amendment:

| | |
|---|---|
| Investigators: | **Centre for Workforce Wellbeing** |
| Sponsor: | **University of Southampton** |
| Funder: | **External restricted funding from Health Education England** |
| Chief Investigator: | Dr Gemma Simons |
| Investigators: | Mr John Jenkins, Miss Emma Boxley, Mrs Aimee O'Neill, Prof. Julia MA Sinclair, Prof. David S Baldwin, |

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## Contents

## 1. Amendment History

| **Amendment No.** | **Protocol Version No.** | **Date issued** | **Author(s) of changes** | **Details of Changes made** |
|---|---|---|---|---|
| | 0.1 | 21/01/2020 | GS | |
| | 0.2 | 11/03/2020 | GS | Format and content altered |
| | 0.3 | 30/03/2020 | GS | Old and new studies made clearer |
| | 0.4 | 02/04/2020 | GS | DS comment no harm in enquiring about psychological symptoms |
| | 0.5 | 07/04/2020 | GS | Response to peer review, further detail on survey analysis |
| | | | | |

## 2. Synopsis

| | |
|---|---|
| **Study Title** | Study Title: Exploring the wellbeing of doctors: a Core Outcome Set to measure wellbeing. |
| **Study Design** | Systematic Review, Doctor Surveys, Delphi Study, Process Mapping |
| **Study Participants** | Doctors, all grades and specialities |
| **Planned Sample Size** | 350 doctors<br>32 experts |
| **Planned Study Period** | 20 minute surveys from May 2020-December 2021, in multiple rounds for those participants taking part in the Delphi survey |
| **Recruiting Centres** | University of Southampton |
| **Chief Investigator** | Dr Gemma Simons |
| **Investigators** | Mr John Jenkins, Miss Emma Boxley, Mrs Aimee O'Neill, Prof. Julia MA Sinclair, Prof. David S Baldwin. |
| **Primary Objectives** | To develop a core outcome set of wellbeing measures for doctors |
| **Secondary Objectives** | To investigate if the Core Outcome Set can be used as part of the Health Education England wellbeing check-in<br>To examine the relationship between the Core Outcome Set of Wellbeing Measures and Burnout, Anxiety and Depression. |
| **Primary Endpoints** | A Delphi consensus on the Core Outcome Set |
| **Secondary Endpoints** | The use of the Core Outcome Set in wellbeing check-ins<br>An understanding of the relationship between wellbeing and burnout, anxiety and depression. |

## 3. Abbreviations

| | |
|---|---|
| C4WW | Centre for Workforce Wellbeing |
| COMET | Core Outcome Measures in Effectiveness Trials |
| COS | Core Outcome Set |
| CRF | Case Report Form |
| GMC | General Medical Council |
| HEE | Health Education England |
| ICHOM | International Consortium for Health Outcome Measures |
| NHS | National Health Service |
| PIS | Participant Information Sheet |
| UHSFT | University Hospital Southampton Foundation Trust |
| UOS | University of Southampton |

## 4. Background and Rationale

### Background

There is never a good time for a pandemic, but Covid 19 has kicked doctors while we were down. Between 50%, [1] and 80% [2] of us were already burnt out. We went on strike, we left traditional training routes, we retired early and now we are asked and volunteering to "doctor on". In the year before Covid 19, policy documents from the Society of Occupational Medicine,[3] the British Medical Association,[4] Health Education England [5] and the General Medical Council [6] recommended vital changes for our wellbeing. These are in danger of being even further from implementation.

There is currently enormous goodwill towards the health professions: our health and safety, and of those we love, is a daily concern around the world. But the lack of adequate provision of Personal Protective Equipment (PPE) has made many doctors and nurses feel that they and their families are considered 'expendable'.[7] We feel shame for thinking of ourselves rather than our patients, guilt for leaving our families and putting them at risk, and worry that people will say we are not doing enough. Many fear we do not have the clinical competence or skill to manage teams in this situation and dread a mistake under the pressure of the volume of work. Not only this, but we risk moral injury through being asked to choose to whom we should devote our limited resources. [8]

Covid 19 is not going to be weathered by a heroic sprint; it is an arduous marathon, which will continue to run long after Covid 19 is no longer of the prime concern. If we are to continue to work when the peaks are over, we must take control of our wellbeing and help colleagues to do the same. [9] Wellbeing is currently defined in terms of the percentage of doctors that are burnt out, anxious, depressed and morally injured. Capturing data repeatedly on how burnt out, anxious, depressed, or morally injured we are as a profession does not assist us in moving forward. We need an operational definition of what wellbeing is, and a core outcome set of measures of wellbeing so we know when we have the optimum conditions to survive and thrive and can share how we achieve it.

### Epistemology

This study utilises the philosophy of 'constructivist epistemology'. Constructivism is a philosophy based on the concept that our knowledge is built from our experiences and social interactions. It differs from empiricism in that it does not assume that our knowledge gained from our experiences is generalizable and considers that our knowledge may not necessarily reflect the external reality. This philosophy does not require external reality to follow a rational structure that can be deduced by intuition and argument, as in rationalism. This is a pragmatic philosophy therefore in that it only agrees that something is "true" as long as it works in predicting the external reality. This philosophy allows for more than observable, empirical, measurable evidence as required in Positivism, to represent external reality. This study aims to measure the wellbeing of doctors using an outcome measure construct, including both quantitative and qualitative methods, to explore the experience of doctors.

### Research Questions

1. What is the definition of wellbeing for doctors?
2. What components of wellbeing have been measured in doctors?
3. How reliable, valid, practical and meaningful are the tools that measure those components of wellbeing?

4. What should the core outcome set of wellbeing measures in medical doctors be and what measurement tools should be used?
5. Can the core outcome set of wellbeing measures be used as part of the Health Education England 2-week wellbeing check-in?
6. What is the relationship between the tools in the Core Outcome Set of wellbeing measures and other measures such as measures of burnout, anxiety and depression?

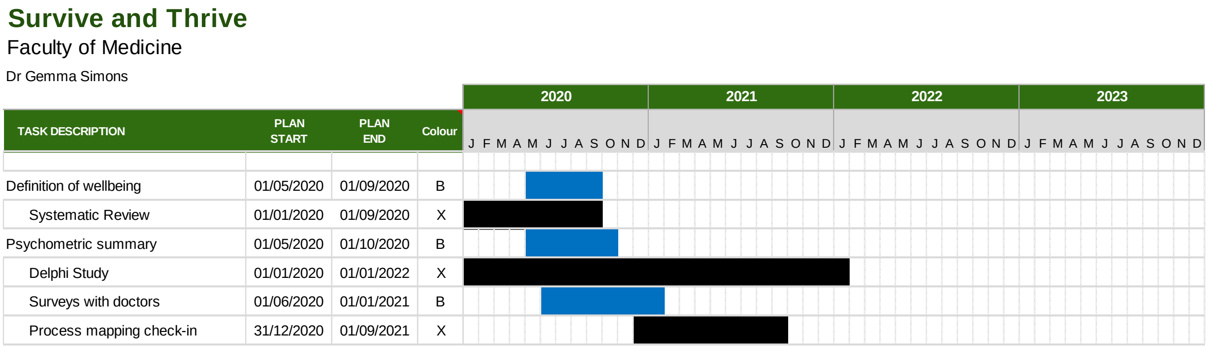
## 5. Aims and objectives

### Aims

- To understand and measure the wellbeing of doctors
- To use varied, innovative methodological approaches
- To build collaborations with national bodies with complementary interests and inform policy at national and organisational levels to improve medical doctors' wellbeing

### Objectives

- To understand the range of definitions of wellbeing in doctor policy and research (May 2020).
- To review which wellbeing measures have previously been used in research and policy for doctors (May 2020).
- To reach a consensus on what core outcome set of measures of wellbeing should be used for doctors (December 2021).
- To explore how the Core Outcome Set of measures of wellbeing fits in with the 2 week wellbeing check-in recommended in the Health Education England Mental Wellbeing Review (December 2021).
- To understand the relationship between the tools in the Core Outcome Set of wellbeing measures and other measures such as measures of burnout, anxiety and depression (December 2020)



**Survive and Thrive**

Faculty of Medicine

Dr Gemma Simons

| TASK DESCRIPTION | PLAN START | PLAN END | Colour |
|---|---|---|---|
| Definition of wellbeing | 01/05/2020 | 01/09/2020 | B |
| Systematic Review | 01/01/2020 | 01/09/2020 | X |
| Psychometric summary | 01/05/2020 | 01/10/2020 | B |
| Delphi Study | 01/01/2020 | 01/01/2022 | X |
| Surveys with doctors | 01/06/2020 | 01/01/2021 | B |
| Process mapping check-in | 31/12/2020 | 01/09/2021 | X |

*Figure 1.Gantt chart for the proposal*

## 6. Project design

This project will be achieved in 5 stages:

1. Systematic Review of the wellbeing measures used for doctors to inform the Delphi study. (Prospero number: 141866. Available at: https://www.crd.york.ac.uk/prospero/)
2. Regional surveys and interviews of doctors to establish their preferences for the purpose, format and frequency, of wellbeing measurement to inform the Delphi study (ERGO number: 49247, IRAS number: 266831, ISRCTN 11949327. Available at: https://doi.org/10.1186/ISRCTN11949327
3. Delphi study among experts in doctors' wellbeing to reach a consensus on the content of the Core Outcome Set of wellbeing measures for doctors (ERGO number: 49246, Comet Registered: 1384. Available at: http://www.comet-initiative.org/Studies/Details/1384

First described in this protocol and ethics application:

4. National online surveys and telephone/video call interviews to establish the components of wellbeing, to test the practicality of core outcome set and understand the relationship between wellbeing measures and other measures for outcomes such as, Burn out, Depression and Anxiety in doctors.
5. Process mapping of how the Core Outcome Set can be integrated into the 2-week wellbeing checks-ins.

## 7. Selection of participants

### Systematic Review

The number of studies included will not be limited by year of publication, or language, to make the search as inclusive as possible. Approximately 250 papers are expected to meet the inclusion criteria.

### Regional surveys and interviews with doctors (ERGO number: 49247, IRAS number: 266831)

Potential problems with recruitment were minimised by inviting participants face to face, at mandatory sessions. Based on NHS Digital NHS Hospital and Community Health Service data were 116,873 doctors in September 2019. [10] The split of opinion amongst doctors on the questions asked was unknown, so to account for anything between a 50/50 split to an 80/20 split, with a 95% confidence interval and ±5% sample error between 245 and 383 surveys needed to be completed.[11] A total of 383 doctors were purposively sampled therefore, and 250 surveys completed.

### Delphi Study (ERGO number: 49246)

For the Delphi study, it is considered that the expertise and stakeholder status of the people involved in the development of a core outcome set is more important than the number involved.[12, 13] Experts are defined in this study as “individuals who have been, or are involved in the concept, design, organisation, delivery, teaching, audit, governance, policy, guidance, or research, of wellbeing in health and social care learners or staff wellbeing”.

Another Core Outcome Set study [14] has determined that including 240 participants in the Delphi survey process would detect a difference of 1-1.5 points between survey rounds on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) scale,[15] with 80% power and $\alpha=5\%$, for a standard deviation of 1.4-4.1.[14] In the Centre for Workforce Wellbeing Delphi study for the Core Outcome Set in doctors, 32 experts were involved in the first round of the survey and 250 doctors of all grades and specialities. The number of experts and doctors available to take part in subsequent rounds will be reduced due to Covid 19, but since the majority of Delphi studies rate expertise above the number in the panel this should not affect the robustness of the methodology.

### National online surveys and telephone/video call interviews

The surveys will be offered to doctors of all grades and specialities through the Royal Colleges, the BMA and other doctor organisations. A subset will be offered interviews.

The null hypothesis is that there is no relationship between wellbeing measures and screening scores for Burnout, Depression and Anxiety. An acceptable level of significance when looking at correlation coefficients will be $p<0.05$. Based on NHS Digital NHS Hospital and Community Health Service data were 116,873 doctors in September 2019 and the breakdown of the numbers in each grade are available to inform purposive sampling. There is no underlying prevalence of wellbeing on which a power calculation may be based, as wellbeing has not been well defined, or measured, in doctors, and is multifaceted. A pragmatic approach would be to power the surveys for the prevalence of burnout, depression and anxiety amongst doctors, with a 95% confidence interval and a 5% precision as the prevalence is expected to be between 10% and 90% for each.

$$n = \frac{Z^2 P(1 - P)}{d^2}$$

n=sample size

Z=the statistic corresponding to the level of confidence, standard normal variate, at 5% type 1 error ($p<0.05$) it is 1.96.

P=the expected prevalence

d=precision or absolute error

In surveys of doctors in the UK [16] and Canada [17] the prevalence of depression in doctors was 63% and 23%. The Survey in the UK was in members of the Doctors Support network and 116 questionnaires were completed, whereas the Canadian study surveyed all doctors in an area and 1805 were completed. In surveys specifically in Consultants in the UK [18] the prevalence was 36% and in Oncology and Palliative Medicine in the UK [19] it was 11%. Based on the mean of these prevalences (33%) the number needed in this survey would be n=340.

$1.96^2$ x 0.33(1-0.33)/$0.05^2$ = 339.75 **(n=340)**

The prevalence of anxiety is reported as 27% in all doctors [20] and 43% in consultants [21] in two UK survey studies. Based on the mean of these prevalences (35%) the number needed in this survey would be n= 350.

1.962 x 0.35(1-0.35)/0.052 = 349.58 (**n=350)**

A systematic review of 14 studies surveying burnout in doctors in the UK found emotional exhaustion, depersonalisation and low personal accomplishment were experienced by between 6% and 54%. [22] It is not clear what percentage were therefore at high, or very high, risk of occupational burnout. A GP Pulse survey of 2230 UK GPs in 2015 found 50% were at high risk of occupational burnout. [23] A BMA Survey in 2018 found 80% of the 4300 UK doctor and medical student responders were at high or very high risk of burnout.[2] The mean of the later two prevalences of risk of burnout is 65%. Based on this prevalence the number needed in this survey would be n=350.

$1.96^2$ x 0.65(1-0.35)/$0.05^2$ = 349.58 **(n=350)**

The overall number needed to complete the surveys is therefore 350 doctors.

The recruitment undertaken face to face at mandatory sessions in the surveys of doctors study (49247) achieved >90% survey completion, compared to 4% when a link to an online survey was emailed. Due to Covid 19 a link to an online survey will have to be the method of recruitment. Assuming only 4% of those invited complete the survey, to get 350 surveys completed (1/0.04 x 350) **8750 doctors** would need to be invited.

## Process Mapping

Utilising all three trusts based in Southampton (University Hospitals Southampton Foundation Trust, Southern Health Foundation Trust, Solent NHS Trust) and the Wessex Health Education England Deanery for General Practice, all of which have differing infrastructure will allow exploration of whether the mapping is generalizable.

## Withdrawal of participants

Participants will be withdrawn from the study if consent is withdrawn. Participants may withdraw at any time for any reason. However, data that has already been anonymised cannot be withdrawn from the study.

## 8. Selection of centre

Online versions of the national surveys will be disseminated through the Royal Colleges, the BMA and other doctor organisations this will make inferences from the data more robust and ensure access to the number of doctors required in the power calculation. The local NHS Trusts (University Hospital Southampton NHS Foundation Trust, Southern Health NHS Foundation Trust and Solent NHS Trust) as well as the Wessex Health Education England Deanery for General Practice are practical centres in which process mapping can be performed.

### The Centre for Workforce Wellbeing

The appropriate research infrastructure is present in the Centre for Workforce Wellbeing, University of Southampton. The Centre for Workforce Wellbeing is a collaboration between Health Education England and the University of Southampton. The Centre for Workforce Wellbeing benefits from a large expert, multidisciplinary steering committee and the academic department of psychiatry in which it sits has a strong history of collaboration with Psychology. The Centre also has strong links with the Royal College of Physicians, through the joint production of the Working Flexibly Toolkit. [24]

### The Investigators

Dr Gemma Simons is a Clinical Research Fellow at the Centre for Workforce Wellbeing and a Speciality Registrar in Rehabilitation Medicine. As an academic clinician, Gemma has worked as Chief Investigator for multicentre clinical research, a Clinical Fellow for NICE Guideline development, and a Cochrane author. It is important to Gemma that the NHS should be an attractive place to work, remain and excel. She aims for her work in the Centre for Workforce Wellbeing to help achieve this.

Mr John Jenkins is a third year medical student doing an intercalated BMedSci research project as part of the Centre for Workforce Wellbeing Team.

Miss Emma Boxley is a third year medical student doing an intercalated BMedSci research project as part of the Centre for Workforce Wellbeing Team.

Mrs Aimee O’Neill is a Senior Research Assistant at the Centre for Workforce Wellbeing. With a background in Cognitive Neuroscience, Psychology, and Organisational Psychology, Aimee has always had an interest in the topic of stress. She hopes that her work at C4WW will generate effective ideas and solutions for the very real problem of healthcare workforce burnout.

Professor Julia Sinclair is Professor of Addiction Psychiatry in the Faculty of Medicine at the University of Southampton. Her clinical roles include developing an integrated alcohol strategy across local clinical services, offering direct clinical care, and work with Regulatory Bodies including the General Medical Council in the UK. She is Chair of the Addiction Faculty of the Royal College of Psychiatrists. Julia’s aim for the C4WW is to develop and disseminate the evidence base to help find solutions to improve the health and wellbeing of health professionals.

Professor David Baldwin is Professor of Psychiatry in the Faculty of Medicine at the University of Southampton, and an Honorary Consultant Psychiatrist with Southern Health NHS Foundation Trust, where he offers a tertiary referral service for patients with mood and anxiety disorders. His research focuses on clarifying the causes and refining the treatment of anxiety and depression. He is Clinical Advisor to the National Clinical Audit of Anxiety and Depression, and Chair of the

Psychopharmacology Committee of the Royal College of Psychiatrists, and is a Past President of Depression Alliance and current Medical Patron of Anxiety UK.

## The Steering Committee

Chair: Prof Iain Cameron (Chair of the Medical Schools Council 2013-2016)

- Dr Nick Broughton (Chief Executive, Southern Health NHS Foundation Trust)
- Prof John Clark (Dean and Director of Education & Quality, HEE South)
- Dame Denise Coia (Chair of Healthcare Improvement Scotland)
- Prof Clare Gerada (Medical Director Practitioner Health Programme)
- Dr Peter Hockey (Professor of Clinical Education and Director of Western Sydney LHD Education Network, University of Sydney)
- Judy Gillow MBE (Director of Nursing, University Hospital Southampton)
- Dr Bernice Knight (National Medical Director's Clinical Fellow)
- Dr Ira Madan (Reader in Occupational Health, King’s College London)
- Dr Paul Sadler (Postgraduate Dean, HEE Wessex)
- Prof Rhema Vaithianathan (Professor of Economics and Co-Director of the Centre for Social Data Analytics, Auckland University of Technology)
- Prof Karen Walker-Bone (Director of Arthritis Research UK/MRC Centre for Musculoskeletal Health, University of Southampton)

## 9. Research methods

### Systematic Review

A systematic review of wellbeing measures used in doctors will inform the items to be discussed in the Delphi Study. The review is registered with Prospero. The Systematic Review will follow the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) Checklist.[25] The Bibliographic databases: MEDLINE, EMBASE, CENTRAL (Cochrane) will be searched as well as subject specific databases: PsycINFO, International Bibliography of Social Science. Two independent authors will assess titles and abstracts. Multiple reports of the same study will be linked. Full-text reports will be assessed for compliance with eligibility criteria.

Once wellbeing measures used in doctors have been extracted in this review they will be listed in a table with their psychometric properties, and other characteristics such as cost and time to complete. This will be presented to the Delphi panel along with other measures of wellbeing, not yet researched in doctors, but potentially useful.

### Regional surveys and interviews of doctors (ERGO number: 49247, IRAS number: 266831

Doctors were identified through their attendance at mandatory Self Care Teaching Sessions offered by the researchers. Doctors were invited to take part in the surveys and provided with a participant information sheet and consent form on paper, and only online if requested, or necessary. Following a face to face study explanation only 4% (6/136) consented to and completed an online survey emailed to them, whereas >90% consented to and completed a paper survey at that time. The total time required for these surveys was described as 30 minutes, but in reality all paper forms were completed within 10 minutes and the mean time for online surveys was 14 minutes. Doctors were asked about their opinions on components of wellbeing, the purpose, format and frequency of measurement using 9-point Likert scales. Participants who took part in the survey were asked if they consent to being contacted to take part in further surveys and interviews and were asked for their email addresses. Participant confidentiality and data protection and governance policy and regulation were followed.

### Delphi study (ERGO number 49247)

This study is using the Delphi technique to reach a consensus core outcome set of measures, as has been recommended by the Alliance for Useful evidence [26] and described in other areas of medicine to ensure that studies are reporting the outcomes of most utility.[27,28] Checklists developed to ensure good Delphi study methodology were used to design this Delphi study.[13,29] Where there is a lack of consensus the panel will be asked to give their rationales in order to facilitate agreement and the panel will be surveyed in further rounds. Once a consensus has been reached for what outcomes should be measured the panel will be presented with the psychometric properties of different measurement tools for that wellbeing component and asked to select the tool they think is the most practical, reliable, valid and meaningful.

### National online surveys and telephone/video call interviews

Doctors who give consent, having read the participant information sheet, will be asked to complete wellbeing measurement tools along with the burnout-screening questionnaire: the Oldenburg Burnout Inventory, the Anxiety and Depression screening tools: the GAD7 and PHQ9 to complete. The Oldenburg Burnout Inventory has been selected, as it was used in the BMA National Burnout survey [2] and measures the Disengagement and Emotional Exhaustion dimensions of burn out. The

GAD7 and PHQ9 were again chosen as they are the most commonly used, separated, and validated screening tools for anxiety and depression.

Doctors who complete the surveys will be invited to take part in a 30-minute semi-structured interview exploring if all components of wellbeing have captured in the core outcome set, or if some components that cannot be quantitatively captured were missed. The purpose of the Core Outcome Set is to have a minimum standard set of measures used in all research into doctors' wellbeing, this should be fit for purpose in the context of the pandemic and beyond. Questions will therefore explore how doctors defined their wellbeing before, during and after the pandemic and what factors determined their wellbeing.

### Process mapping

How the Core Outcome Set is given to doctors and whether this should be offered before, or during a 2-week check-in, will be explored through looking at the 2-week check in process, and the infrastructure available to support it. The frequency, at which check-ins would occur based on the Health Education England suggestion of having one at the start of each new placement, will be calculated.  Aspects such as the competence required by those undertaking the check-in, the services available to signpost to, the length of time needed for check-ins, and potential mitigating activity will be explored.

### Data Collection

The data collection will be the overall responsibility of the Chief Investigators at the Centre for Workforce Wellbeing (Dr Gemma Simons). Data collection may be delegated to investigators who have been appropriately trained.

## 10. Data analysis

### Systematic Review

The outcomes that will be captured in this review will be:

- the wellbeing outcome used
- the measurement tool used

A kappa statistic for agreement between the two authors will be reported. If eligibility is unclear, the corresponding author will be contacted for clarification and further results if necessary. A list of excluded studies at the full text stage will be available and a PRISMA flow diagram will be utilised to display results.[25]

### Regional surveys and interviews of doctors

The size of the group of doctors approached to answer the surveys will be displayed, as will the number who consented to take part in the survey and the number who answered each question. Demographic data will be displayed as the percentage of participants that chose each category. Bar graphs demonstrating the answer options on one axis and the percentage of participants that chose that score on the vertical axis will be displayed. Correlation co-efficients to show the relationship between measures will be displayed. Latent class analysis will be performed to see if certain categories of responder exist beyond demographic groups.

### Delphi Survey

The a priori definition of when a consensus has been reached about an outcome measure is when 75% of the group vote for it. This is based on the use of this percentage as an acceptable cut off (or higher than an acceptable cut off) by a number of published studies looking to reach a consensus on outcome measurement for obesity,[30] appendicitis in children,[31] primary care,[32] and multiple myeloma.[33]

The number of participants invited to the survey and the number who completed them will be displayed. The number that answered each question will be displayed, as well as what percentage this was of those invited. Bar graphs demonstrating the answer options, such as the 9-point Likert scale on the horizontal axis and the percentage of participants that chose that score on the vertical axis will be displayed. Where a 9-point Likert scale is used and 75% of participants have scored an outcome 1-3, this outcome will be considered of limited importance. Where an outcome is score 4-6 by 75% of participants, an outcome will be considered important, but not critical. When an outcome is scored 7-9 by 75% of participants, it will be considered critical. This is in line with the statistical methodology of Delphi studies used to choose outcome measures.[34-36]

The Standards for Reporting Qualitative Research (SRQR) will be used.[37]

### National surveys and interviews with doctors

The size of the group of doctors approached to answer the surveys, will be displayed, as will the number who consented to take part in the survey and the number who answered each question. Baseline demographic data will be displayed and as percentages of participants that chose each category, with significance levels. Bar graphs demonstrating the answer options on one axis and the percentage of participants that chose that score on the vertical axis will be displayed. The relationship between the measurement tools in the Core Outcome Set will be analysed using correlation coefficients.  The relationship between the Core Outcome Set and the mental health screening measures will be measured with correlation coefficients. Latent class analysis will be performed to see if certain categories of responder exist beyond demographic groups.

Thematic and discourse analysis will allow answers to open questions in the interviews to be summarised and presented.

### Process mapping

A process map, learning outcomes for training, a protocol for the wellbeing check-in and onward signposting infrastructure needed will be listed. A tool to capture length of check-in and mitigating activity will be designed.

## 11. Ethics

### Quality control and assurance

The study will be conducted in accordance with the current revision of the Declaration of Helsinki. It will be carried out in accordance with Good Clinical Practice (GCP) as set down in ICH E6. Only the approved protocol and its amendments will be used.

### Consent

All participants are expected to have the capacity to provide consent. All participants will be given a Participant Information Sheet. Consent and Participant Information will either be on I-survey, or on paper, in line with Public Health England (PHE) guidance.

### Participant Confidentiality

Doctors completing the survey through I-survey can choose to complete the survey anonymously, or to provide a name and email to be contacted about further surveys and/or interview. The participants will be identified by a study specific participant number. Their name and any other identifying detail will NOT be included in any study data electronic files, or publications. I-survey captures IP addresses, but these will be removed from all study files by the researchers. All question responses will be anonymized to maintain participant confidentiality. The investigators involved with this study will not disclose, or use for any purpose other than performance of the study, any confidential information disclosed to them for the purpose of the study. Decryption files will only be available to the Investigators.

To ensure that doctors across all demographics are represented in this study, special category data will be requested. This data is also necessary to ensure that the wellbeing measures work for doctors across all demographics. Data will not be presented at an individual level, only group analysis will be presented and therefore it will not be possible to identify individuals from their demographics.

### Study Governance

As part of the University of Southampton Ethics and Research Governance process, peer review by 2 external researchers is required and has been obtained.

### Steering Committee

The research activity of the Centre for Workforce Wellbeing is overseen by its Steering Committee, which meets every 6 months.

### Inspection of Records

Investigators and institutions involved in the study will permit study related monitoring and audit on behalf of the sponsor, Ethics Committee review, and regulatory inspection(s). In the event of an audit or monitoring, the Investigator agrees to allow the representatives of the sponsor direct access to all study records and source documentation. In the event of regulatory inspection, the Investigator agrees to allow inspectors direct access to all study records and source documentation.

### Investigator Responsibilities

The Chief Investigator will be responsible for the overall conduct of the study and compliance with the protocol and any protocol amendments, in accordance with the principles of ICH GCP.

Responsibilities may be delegated to an appropriate member of investigator team. The Chief Investigator will be responsible for ensuring that the approved consent procedures are followed before any protocol specific procedures are carried out, and for ensuring that all delegated investigators are familiar with the protocol, the study requirements, and their study related duties, as well the quality of the data. Prior to beginning the study, each Investigator will be asked to provide the following: Curriculum vitae (CV) signed and dated by the Investigator indicating that it is accurate and current, and evidence of current GCP training.

## 12. Governance, data handling and record keeping

This is an investigator initiated and led study. It is sponsored by the University of Southampton. The Centre for Workforce Wellbeing Steering Committee will provide oversight to the research activities of investigators. Amendments to the protocol will be submitted to ERGO, the University of Southampton ethics and research governance online system prior to participants being enrolled into an amended protocol.

The participants will be identified by a study specific participant number. Their name and any other identifying detail will NOT be included in any study data electronic file. The decryption key files will be the only place a participant is linked to their participant number.

### Data Protection

All electronic data will be stored on the secure University of Southampton network and require password input for access. The study will comply with the Data Protection Act, which requires data to be anonymised as soon as it is practical to do so. The participants' survey answers and transcripts will be identified by a study specific participant number. Their name and any other identifying detail will NOT be included in any study data electronic file and audio recording files will be password protected. A validated data entry system will be utilised in this study and has a standard operating procedure. The database will have an audit trail.

### Data Protection Privacy Notice

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when a participant agrees to take part in a research study, we will use information about them in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page).

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses personal data when a person takes part in one of our research projects and can be found at http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which a participant can be identified directly, it will not be disclosed to anyone else without their consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the ‘Data Controller’ for this study, which means that they are responsible for looking after participant information and using it properly. The University of Southampton will keep identifiable information for 15 years after the study has finished after which time any link between the person and their information will be removed.

To safeguard participant rights, we will use the minimum personal data necessary to achieve our research study objectives. Participant data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with personal data that would not be reasonably expected.

### Study Record Retention

All study documentation will be kept for up to 15 years.

## 13. Financing and Insurance

Restricted grant award from Health Education England.

University of Southampton is the sponsor for the study.

## 14. Publication Policy

A report containing the results of this study will be written, presented at scientific meetings and possibly published in a scientific journal. Medical journals, such as the BMJ, and medical conferences, such as the International Conference of Physician Health, will be targeted. The results may also be presented in the Centre for Workforce Wellbeing blog and twitter accounts.

## References

1. Matthew-King A. Revealed: the rising tide of GP burnout as NHS cuts support. Pulse. http://www.pulsetoday.co.uk/ your-practice/battling-burnout/revealed-the-rising-tideof-gp-burnout-as-nhs-cuts-support/20010133.fullarticle. Published 2015. Accessed June 14, 2018.

2. British Medical Association. Caring for the mental health of the medical workforce. Available at: https://www.bma.org.uk/-/media/files/pdfs/collective%20voice/policy%20research/education%20and%20training/20190196%20bma%20mental%20health%20survey%20report.pdf?la=en [Accessed 27/01/2020].

3. Society of Occupational Medicine. What could make a difference to the mental health of UK doctors? Available at: https://www.som.org.uk/sites/som.org.uk/files/What_could_make_a_difference_to_the_mental_health_of_UK_doctors_LTF_SOM.pdf [Accessed 27/01/2020].

4. British Medical Association. Supporting health and wellbeing at work. Available at: https://www.bma.org.uk/collective-voice/policy-and-research/education-training-and-workforce/supporting-health-and-wellbeing-at-work [Accessed 27/01/2020].

5. Health Education England. NHS Staff and Learners' Wellbeing Commission. NHS Staff and Learners Wellbeing Review. Available at: https://www.hee.nhs.uk/sites/default/files/documents/NHS%20(HEE)%20-%20Mental%20Wellbeing%20Commission%20Report.pdf [Accessed: 27/01/2020].

6. General Medical Council. Caring for doctors, Caring for patients. Available at: https://www.gmc-uk.org/-/media/documents/caring-for-doctors-caring-for-patients_pdf-80706341.pdf [Accessed 27/01/2020].

7. Locke T. COVID-19 Medscape UK PPE Poll: 7 in 10 Lack Supplies. Medscape News UK. Available at: https://www.medscape.com/viewarticle/927344?nlid=134642_5223&src=wnl_newsalrt_uk_200323_MSCPEDIT&uac=100345AJ&impID=2321565&faf=1 [Accessed: 23/03/2020]

8. Greenberg N et al. Managing mental health challenges faced by healthcare workers during covid-19 pandemic. BMJ 2020;368:m1211. Available at: http://dx.doi.org/10.1136/bmj.m1211 [Accessed 26/02/2020]

9. Unadkat S, Farquhar M. Self-care for doctors during the covid-19 crisis. BMJ 2020;368:m1150 [Accessed 29/03/2020]

10. NHS Digital NHS Hospital and Community Health Service data. NHS Workforce statistics. September 2019. Available at: https://digital.nhs.uk/data-and-information/publications/statistical/nhs-workforce-statistics/september-2019 [Accessed 08/01/2020]

11. Price J H, et al. Power Analysis in Survey Research: Importance and Use for Health Educators. American Journal of Health Education 2005; 36(4): 202-209. DOI: 10.1080/19325037.2005.10608185.

12. Powell C. *The Delphi technique: myths and realities*. J Adv Nursing 2003; 41(4): 376-382.

13. Williamson P R, et al*. The COMET Handbook. Version 1.0.* Trials 2017; 18(3): 280.

14. Rose L, et al. *Development of core outcome sets for effectiveness trials of interventions to prevent and/or treat delirium (Del-COrS): study protocol*. BMJ Open 2017; 7: e016371. doi: 10.1136/bmjopen-2017-016371.

15. Guyatt G H, et al. *GRADE guidelines: 4. Rating the quality of evidence–study limitations (risk of bias)*. Journal of clinical epidemiology 2011; 64(4): 407-15.

16. Miller, L. (2008). Doctors, their mental health and capacity to work. Occupational Medicine, 59, 53–55.

17. Hsu, K., & Marshall, V. (1987). Prevalence of depression and distress in a large sample of Canadian residents, interns, and fellows. American Journal of Psychiatry, 144, 1561–1566.

18. Khan A, Teoh KR-H, Islam S, Hassard J. Psychosocial Work Characteristics, Burnout, Psychological Morbidity Symptoms and Early Retirement Intentions: A Crosssectional Study of NHS Consultants in the United Kingdom. BMJ Open. 2018.

19. Berman R, Campbell M, Makin W, Todd C. Occupational stress in palliative medicine, medical oncology and clinical oncology specialist registrars. Clin Med. 2007;7(3):235-242. doi:10.7861/clinmedicine.7-3-235.

20. Medisauskaite A. Understanding and improving the occupational health of medical doctors: A systematic review and meta-analysis of prevalence and a randomised controlled trial of an intervention Asta Medisauskaite This thesis is submitted to Birkbeck, University of London. 2018; (February).

21. Khan A, Teoh KR-H, Islam S, Hassard J. Psychosocial Work Characteristics, Burnout, Psychological Morbidity Symptoms and Early Retirement Intentions: A Crosssectional Study of NHS Consultants in the United Kingdom. BMJ Open. 2018.

22. Imo UO. Burnout and psychiatric morbidity among doctors in the UK: A systematic literature review of prevalence and associated factors. BJPsych Bull. 2017;41(4):197-204. doi:10.1192/pb.bp.116.054247.

23. Matthew-King A. Revealed: the rising tide of GP burnout as NHS cuts support. Pulse. http://www.pulsetoday.co.uk/ your-practice/battling-burnout/revealed-the-rising-tideof-gp-burnout-as-nhs-cuts-support/20010133.fullarticle. Published 2015. Accessed June 14, 2018.

24. Simons G, Gordon H. *Working Flexibly: A Toolkit*. Royal College of Physicians. Available at: https://www.rcplondon.ac.uk/projects/outputs/working-flexibly-toolkit [Accessed 05/03/2020].

25. Moher D, et al. *Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement*. Syst Rev 2015; 4(1) https://doi.org/10.1186/2046-4053-4-1.

26. Breckon J, Dodson *J. Alliance for useful evidence. Using evidence. What works? A discussion paper.* Available at: https://www.alliance4usefulevidence.org/publication/using-evidence-what-works-april-2016/. [Accessed 05/06/19].

27. Core Outcome Measures in Effectiveness Trials (COMET) Initiative. *Resources – Database*. Available at: http://www.comet-initiative.org/ [Accessed 27/01/2020].

28. International Consortium for Health Outcomes Measurement (ICHOM). *Our work- Standard sets*. Available at: https://www.ichom.org/ [Accessed 27/01/2020].

29. Sinha I P, et al. Using the Delphi technique to determine which outcomes to measure in clinical trials: recommendations for the future based on a systematic review of existing studies. PLoS Med 2011; 8(1): e10003.

30. Vogel C, et al. A delphi study to build consensus on the definition and use of big data in obesity research. Available at: https://www.nature.com/articles/s41366-018-0313-9.pdf. [Accessed 23/05/19].

31. Knaapen M, et al. Establishing a core outcome set for treatment of uncomplicated appendicitis in children: study protocol for an international Delphi survey. BMJ Open 2019; 9: e028861. doi: 10.1136/bmjopen-2018-028861.

32. Santaguida P, et al. Protocol for a Delphi consensus exercise to identify a core set of criteria for selecting Health Related Outcome Measures (HROM) to be used in primary health care. BMC Family Practice 2018; 19: 152.

33. Blade J, et al. Defining a set of standardised outcome measures for newly diagnosed patients with multiple myeloma using the Delphi consensus method: the IMPORTA project. BMJ Open 2018; 8: e018850. doi: 10.1136/bmjopen-2017-018850.

34. Harman N L, et al. The importance of integration of stakeholder views in core outcome set development: otitis media with effusion in children with cleft palate. PLoS One 2015; 10(6): e0129514.

35. Needham D M. Improving long-term outcomes research for acute respiratory failure. 2016. Available at: https://www.comet-initiative.org/studies/details/360 [Accessed 30/05/19].

36. Mease P J, et al. Fibromyalgia syndrome. J Rheumatol 2005; 32(11): 2270–7.

37. O'Brien B C, et al. Standards for reporting qualitative research: a synthesis of recommendations. Acad Med 2014; 89(9): 1245-1251.