

Survive and Thrive: exploring the wellbeing of doctors in a post-COVID-19 era

Submission date 21/04/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 04/05/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/08/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

There is never a good time for a pandemic, but COVID 19 has kicked doctors while they were down. Between 50% and 80% were already burnt out. They went on strike, left traditional training routes, retired early and now are asked and volunteering to “doctor on”. In the year before COVID-19, policy documents from the Society of Occupational Medicine, the British Medical Association, Health Education England and the General Medical Council recommended vital changes for their wellbeing. These are in danger of being even further from implementation.

There is currently enormous goodwill towards the health professions: their health and safety, and of those they 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’. They feel shame for thinking of themselves rather than their patients, guilt for leaving their families and putting them at risk, and worry that people will say they are not doing enough. Many fear they 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 they risk moral injury through being asked to choose to whom we should devote their limited resources.

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 doctors are to continue to work when the peaks are over, they must take control of their wellbeing and help colleagues to do the same. 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 they are as a profession does not assist them in moving forward. Doctors need an operational definition of what wellbeing is, and a core outcome set of measures of wellbeing so they know when they have the optimum conditions to survive and thrive and can share how they achieve it.

The aims of this study are:

1. To understand the range of definitions of wellbeing in doctor policy and research
2. To review which wellbeing measures have previously been used in research and policy for doctors
3. To reach a consensus on what core outcome set of measures of wellbeing should be used for doctors

4. 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
5. 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

Who can participate?

Doctors of all grades and specialities

What does the study involve?

Participants will see the advertised link to the research surveys, or be told about the survey verbally. If they choose to take part in a survey, a participant information sheet will be displayed. They will complete a consent form, case report form and demographic form. The main body of the surveys will also be completed online. The whole process will take a maximum of 20 minutes. Doctors can opt to take part in further online surveys and/or a 30-minute interview. The surveys and interviews will be run from May 2020 to December 2020.

What are the possible benefits and risks of participating?

The study aims to improve understanding of the measurement of doctors' wellbeing in the hope that interventions can be adequately designed, analysed and evaluated and money only spent on those that seem likely to be effective and feasible in practice. There are no anticipated risks associated with answering the wellbeing survey questions, but the results of the burnout, anxiety and depression surveys may indicate that further investigation is required. The tools selected are not diagnostic but screening tools, and no harm has been demonstrated in the literature through asking about psychological symptoms. It will not be possible to email all participants as they do not have to provide an email address and the data will not be analysed quickly enough to advise individuals to seek further investigations. At the end of the survey, doctors will be given details of the BMA 24/7 confidential counselling and peer support service (+44 (0)330 123 1245) and advised to contact their GP if they are concerned about their mental health.

Where is the study run from?

The national surveys will be disseminated through the Royal Colleges and other doctor organisations. The study will run from the Centre for Workforce Wellbeing, University of Southampton (UK)

When is the study starting and how long is it expected to run for?

January 2020 to December 2021

Who is funding the study?

Health Education England (UK)

Who is the main contact?

Dr Gemma Simons

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Contact information

Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

55747

Study information

Scientific Title

Survive and Thrive: exploring the wellbeing of doctors in a post-COVID-19 era: a Core Outcome Set to measure wellbeing

Study objectives

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?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 09/06/2020, University of Southampton Ethics and Governance (Research Integrity and Governance Team, University of Southampton, 2031, Building 28, Highfield Campus, Southampton SO17 1BJ, UK; +44(0) 23 80598848; rgoinfo@soton.ac.uk), ref: 55747

Study design

Mixed methods study that utilises systematic review, Delphi surveys, and doctor surveys and interviews as part of the Core Outcome Set development process

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Internet/virtual

Study type(s)

Other

Participant information sheet

<https://www.isurvey.soton.ac.uk/36956>

Health condition(s) or problem(s) studied

Wellbeing in a post-COVID-19 era

Interventions

This project will be achieved in five stages:

1. Systematic review of the wellbeing measures used for doctors to inform the Delphi study

(Available at: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42020141866)

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 Project ID 266831, ISRCTN11949327, 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>)

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 burnout, depression and anxiety in doctors

5. Process mapping of how the Core Outcome Set can be integrated into the Health Education England 2-week wellbeing checks-ins

Participants will see the advertised link to the research surveys, or be told about the survey verbally. If they choose to take part in a survey, a participant information sheet will be displayed. They will complete a consent form, case report form and demographic form. The main body of the surveys will also be completed online. The whole process will take a maximum of 20 minutes. Doctors can opt to take part in further online surveys and/or a 30-minute interview. The surveys and interviews will be run from May 2020 to December 2020.

Intervention Type

Other

Primary outcome measure

A minimum set of measures of wellbeing for doctors, a Core Outcome Set, is being developed through a systematic review, Delphi study and doctor surveys. The Core Outcome Set of wellbeing measures will form the primary outcomes. Which questionnaires these will be determined in the first part of this study. They will be measured during the pandemic, separated by a month for those who consent to take part in more than one survey, and after the pandemic.

Secondary outcome measures

Measured during the pandemic, separated by a month for those who consent to take part in more than one survey, and after the pandemic:

1. Burnout measured using the Oldenburg Burnout Inventory
2. Anxiety, measured using the Generalised Anxiety Disorder 7 Questionnaire
3. Depression, measured using the Patient Health Questionnaire 9

Overall study start date

21/01/2020

Completion date

31/12/2021

Eligibility

Key inclusion criteria

Doctors of any grade and from any speciality

Participant type(s)

Health professional

Age group

Adult

Sex

Both

Target number of participants

350

Key exclusion criteria

People who are not doctors

Date of first enrolment

15/08/2020

Date of final enrolment

31/10/2020

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Centre for Workforce Wellbeing

Academic Centre, College Keep

4-12 Terminus Terrace

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Sponsor information

Organisation

University of Southampton

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Sponsor type

University/education

Website

<http://www.southampton.ac.uk/>

ROR

<https://ror.org/01ryk1543>

Funder(s)

Funder type

Government

Funder Name

Health Education England

Results and Publications

Publication and dissemination plan

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.

Intention to publish date

30/09/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V0.5	07/04/2020	04/05/2020	No	No

