

The COVID-19 Emergency Response Assessment Study: a survey of the psychological health of frontline doctors in the UK and Ireland during the coronavirus pandemic

Submission date 13/04/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 23/04/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/07/2021	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

COVID 19 is a new form of viral illness which emerged from Wuhan, China, in late 2019. The disease has spread internationally (known as a pandemic) and has now created a public health emergency in the UK and Ireland. From the beginning of March 2020 significant steps have been taken to respond to the threat of the Coronavirus; many healthcare services have been extensively reorganised in preparation for what is expected to be one of the biggest challenges in a generation. Over the coming weeks and months, the UK and Ireland are expected to manage significant numbers of patients with COVID 19, with potential progressive impact on health services and staff providing care.

Frontline medical staff (ED, ICU and Anaesthetic doctors) already experience significant pressure in their day to day work, and it is likely that this staff group will be required to provide initial and ongoing care to patients arriving at hospital with suspected or confirmed COVID-19. This is likely to lead to increased demands at work, which may have a negative effect on staffs' psychological wellbeing. Understanding any psychological impact of the spread of COVID 19 on frontline staff is therefore important in planning and delivering support services and to inform planning for future pandemics.

This study aims to assess the self-reported psychological wellbeing of doctors working in acute and critical care across the UK and Ireland during the COVID-19 pandemic and examine factors that may relate to psychological wellbeing. This will be achieved by issuing the General Health Questionnaire 12 (GHQ 12), at the beginning (acceleration), middle (peak) and near the end (deceleration) of the pandemic. And the Impact of Events Scale – Revised (IES-R) at the middle (peak) and near the end (deceleration) of the pandemic. Further questions will focus on important factors including work-related and personal factors.

Who can participate?

Participants will be invited if they are working as a doctor within an ED, ICU or Anaesthetics in the UK and Ireland

What does the study involve?

Participants will be asked to complete three surveys exploring their mental health and wellbeing and providing some demographic information. Participants will be asked to complete these surveys at three time points: at the acceleration, peak, and deceleration phases of the COVID-19 pandemic wave.

What are the possible benefits and risks of participating?

Full analysis of data will help identify how emergency staff can be better supported during future disease outbreaks.

Some of the issues explored in the surveys will be sensitive, and this may be a challenging time for doctors. Information about sources of support that participants might wish to contact have been included within the initial survey.

Where is the study run from?

North Bristol NHS Trust (UK)

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

From March 2020 to October 2020

Who is funding the study?

Royal College of Emergency Medicine (UK)

Who is the main contact?

Dr Tom Roberts
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Contact information

Type(s)

Public

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

281944

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

V5.0, IRAS 281944

Study information

Scientific Title

The COVID-19 Emergency Response Assessment (CERA) Study; a prospective longitudinal survey of frontline Doctors in the UK and Ireland

Acronym

The CERA Study

Study objectives

Doctors in Emergency Care may encounter high levels of psychological distress and trauma. This study aims to understand the prevalence and degree of psychological trauma and distress on Doctors on dealing with the COVID-19 pandemic outbreak.

Ethics approval required

Old ethics approval format

Ethics approval(s)

HRA and Health and Care Research Wales (HCRW) stated that no ethics approval was required.

1. Approved 24/03/2020, Ethics (medical research) committee office of Children's health Ireland at Crumlin (Dublin, Ireland D12 N512; +353 014096100; no email provided), ref: GEN/806/20
2. Approved 16/03/2020, University of Bath (Claverton Down, Bath, BA2 7AY, UK; no tel. provided, no email provided), ref: 4421

Study design

Prospective longitudinal survey

Primary study design

Observational

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Psychological distress and trauma in doctors treating patients with COVID-19 (SARS-CoV-2 infection)

Interventions

Participants will be asked to complete three participant surveys over the three phases of the COVID-19 pandemic wave at the acceleration, peak, and deceleration. These surveys will be the General health questionnaire - 12 (GHQ-12), the Impact of Events Scale - Revised (IES-R), and a survey designed by the investigators of participants' personal, demographic and occupational information.

Intervention Type

Other

Primary outcome(s)

1. The General Health Questionnaire-12 score from surveys administered at the acceleration, peak and declaration of the COVID-19 pandemic
2. The Impact of Events Scale-Revised from surveys administered at the acceleration, peak and deceleration of the COVID-19 pandemic (phase 2 and 3 surveys)

Key secondary outcome(s)

1. Personal and professional factors contributing to psychological wellbeing assessed using a survey designed by the investigators at the acceleration, peak and deceleration phase of the pandemic
2. The incidence of self-reported COVID-19 infection and self-isolation amongst frontline Doctors, and to evaluate any association with psychological wellbeing (using the above questionnaires)
3. Regional and national variation of psychological distress and trauma in doctors within the UK and Republic of Ireland (using the above questionnaires)

Completion date

01/10/2020

Eligibility

Key inclusion criteria

Working as a doctor within an ED, ICU or Anaesthetics in the UK and Ireland at the time of the study commencement

Participant type(s)

Health professional

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

5440

Key exclusion criteria

1. Doctors whose main place of employment at the point of study commencement is not the ED, ICU or Anaesthetics.
2. Non-Doctors working in ED, ICU or Anaesthetics

Date of first enrolment

18/03/2020

Date of final enrolment

01/10/2020

Locations

Countries of recruitment

United Kingdom

England

Ireland

Study participating centre

North Bristol NHS Trust

Southmead Rd

Bristol

United Kingdom

BS10 5NB

Sponsor information

Organisation

North Bristol NHS Trust

ROR

<https://ror.org/036x6gt55>

Funder(s)

Funder type

Research organisation

Funder Name

Royal College of Emergency Medicine

Alternative Name(s)

RCEM

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2021	12/04/2021	Yes	No
Results article		09/07/2021	12/07/2021	Yes	No
Protocol article	protocol	11/08/2020	17/08/2020	Yes	No
Participant information sheet			05/05/2020	No	Yes