ISRCTN10666798 https://doi.org/10.1186/ISRCTN10666798

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

Registration date
23/04/2020

Overall study status
Completed

Last Edited
12/07/2021

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
tern@rcem.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Tom Roberts

ORCID ID
https://orcid.org/0000-0003-4991-974X

Contact details
7-9 Bream Buildings
London
United Kingdom
EC4A 1DT
+44 (0)7894234121
tern@rcem.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
281944

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
See additional files

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 measure
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)

Secondary outcome measures
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)

Overall study start date
12/03/2020

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

Age group
Adult

Sex
Both

Target number of participants
6,000-7,000

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
England

Ireland

United Kingdom

Study participating centre
North Bristol NHS Trust
Southmead Rd
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
North Bristol NHS Trust

Sponsor details

Southmead Rd
Bristol
England
United Kingdom
BS10 5NB
+44 (0)117 41 49330
researchsponsor@nbt.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.nbt.nhs.uk/

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

Publication and dissemination plan
On completion of each phase of the study an interim study report will be prepared for submission to a peer reviewed scientific journal. On completion of the whole study, the data will be analysed and tabulated, and a Final Study Report prepared.

The Final Study Report will be subsequently condensed into manuscript format for submission to a peer reviewed scientific journal. The work will also be submitted for presentation at a relevant scientific meeting. Identifiable personal data will not be used during publication of the results.

Funding and supporting bodies will be acknowledged on any reports or publications. Publication recognition will be conducted in accordance with the TERN publication policy.

Authorship will be via the CERA Trial Management Group members and network collaboration (TERN, PERUKI, RAFT and TRIC), and collaborators listed according to journal guidelines.

Intention to publish date
01/05/2020

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?
Participant information sheet			05/05/2020	No	Yes
Protocol article	protocol	11/08/2020	17/08/2020	Yes	No
Results article		01/06/2021	12/04/2021	Yes	No
Results article		09/07/2021	12/07/2021	Yes	No