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The EPIC Project: the mental and physical health impact of the COVID-19 pandemic on healthcare professionals, patients and the general public

Submission date
11/03/2021

Recruitment status
No longer recruiting

Registration date
24/06/2021

Overall study status
Completed

Last Edited
03/04/2024

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The WHO declared the coronavirus disease COVID-19 to be a new outbreak declaring a public health emergency of a global scale and concern. By March 2020' the pandemic was declared as a national healthcare emergency in many countries. Equally, the psychological stress generated as a direct result of this pandemic was varied and concerning at the same time. The wellbeing of healthcare workers who are also patients with long-term health conditions is the most concerning of all as coping strategies, such as ensuring sufficient rest during work and/or between shifts, consumption of healthy meals, engaging in physical activity and maintaining communication with friends and family, are variable due to personal and professional circumstances. The long-term impact of the pandemic could worsen mental and physical wellbeing. Given the unique and unprecedented scenarios many have faced, there is a requirement for research to be conducted to provide extensive interventions. Whilst current and immediate strategies appear to focus on providing interventions using digital or telepsychiatry platforms, there is a lack of healthcare professional specific mental healthcare support. In addition to this, there is also a lack of mental healthcare support available for patients with chronic long-term healthcare conditions who may have untreated mental health symptoms and /or undiagnosed conditions such as mood disorders or depression. The aim of this study is to gather data to assess the mental health impact of the COVID-19 pandemic on patients, the general public and healthcare professionals.

Who can participate?
Patients, the general public and healthcare professionals

What does the study involve?
Digital self-reporting data collection will be used at the start of the study and after 3 months to evaluate the autonomic dysfunction associated with those infected with COVID-19 compared with those who were not infected by COVID-19.

What are the possible benefits and risks of participating?
Participants will inform the impact of autonomic dysfunction in terms of COVID leading to long COVID syndrome which is yet to be clinically defined and confirmed as the pandemic is still ongoing. There is minimal risk for participants. If any participant is scoring high on any of the validated questionnaires used, they will be informed to contact their GPs for relevant clinical support as often autonomic dysfunction could remain undiagnosed.

Where is the study run from?
Southern Health NHS Foundation Trust in partnership with University College London Hospitals (UK)

When is the study starting and how long is it expected to run for?
April 2020 to Janaury 2022

Who is funding the study?
Southern Health NHS Foundation Trust (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The EPIC Project: the mental and physical health impact of the COVID-19 pandemic on healthcare professionals, patients and the general public

Acronym
EPIC

Study objectives
The COVID-19 pandemic has had a mental health impact on multiple cohorts. The mental health impact varies across multiple cohorts due to many different factors including any physical manifestations associated directly or indirectly with COVID-19.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not applicable - evidence synthesis does not require ethics approval

Study design
Platform project with multiple workstreams and substudies. The initial portion of the project will focus on a comprehensive evidence synthesis with a novel mixed methods methodology. All substudies/workstreams will have specific clinical and scientific outcome measures.

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
This is a multi-morbid research project that will include patients, non-clinical populations and healthcare professionals. Clinical populations associated with this project include any condition associated with obstetrics and gynaecology, neurology, pain disorders, cardiovascular diseases and psychiatry.

Interventions
The initial sub-studies associated will gather observational data to determine any mental and physical health sequelae. Diagnostic assessments and/or treatment interventions used will be identified and reported. A systematic method will be used to synthesise both peer review and published material as well as prospective data gathered through the EPIC project. Protocols associated with each systematic method will be developed and published.

EPIC is a multifaceted, multi-morbid epidemiological study to determine the prevalence of mental health impact of COVID and long-COVID due to the pandemic. The sample population will include healthcare professionals, patients and the general public. The first workstream will include all participants that may have any neurological and/or neuro-psychiatric and/or pain symptomatologies to determine autonomic dysfunction within the sample. This will have a recruitment period of 8 months and over the course of the next 4 months the data analysis would be conducted. The self-reported and administered questionnaire will be completed at baseline and at month 3 with a follow-up at month 6.

The second workstream will be for healthcare professionals, patients and the general public who demonstrate any gynaecological/obstetric conditions although this will not open until the autonomic dysfunction data has been analysed and published. The methodology will remain the same for this part as well.

Intervention Type
Mixed

Primary outcome(s)
Mental health impact based upon autonomic dysfunction (COVID vs long COVID) measured using a novel self-reported instrument at baseline and month 3

Key secondary outcome(s))
1. Pain outcomes associated with COVID vs long COVID measured using a novel self-reported instrument at baseline and month 3
2. Neuropsychiatric outcomes associated with COVID vs long COVID measured using a novel self-reported instrument at baseline and month 3

Completion date
20/01/2022

Eligibility

Key inclusion criteria
All participants required for each sub-study will be noted within the relevant participant information sheet/informed consent form. The sample population will include healthcare professionals, patients and the general public.

Participant type(s)
Healthy volunteer, Patient, Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

All

Key exclusion criteria
Under 18 years of age

Date of first enrolment
30/05/2021

Date of final enrolment
30/12/2021

Locations

Countries of recruitment
United Kingdom

Canada

India

Nigeria

Pakistan

Study participating centre
Not applicable - this is a digital clinical trial
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-
United Kingdom
-

Sponsor information

Organisation
Southern Health NHS Foundation Trust

ROR
https://ror.org/03qesm017

Funder(s)

Funder type
Government

Funder Name
NIHR Research Capability Funding

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications		06/04/2021	13/02/2024	Yes	No
Other publications		17/08/2023	13/02/2024	Yes	No
Other publications		25/07/2023	13/02/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes