

Pandemic tracking of healthcare workers cohort and questionnaire study

Submission date 19/01/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/04/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/02/2022	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The WHO characterised COVID-19 as a pandemic after 118,000 cases and 4,291 deaths. Cases have continued to rise and now 400,000 deaths have been reported. National guidance has recommended physical distancing to reduce transmission of the virus, although healthcare workers are expected to continue with normal patterns of working in order to care for those with the virus. There is early evidence that there is up to a 12-fold increased risk of SARS-CoV-2 infection in healthcare workers, and there have been 245 reported fatalities in UK healthcare workers.

In an environment where there is increased exposure, it is important to understand the occupational, personal, medical and genetics factors which predispose healthcare workers to contracting the virus and make individuals at risk of poor outcomes. There have been a number of epidemiological and serological studies which have identified risk factors such as age, gender and certain pre-existing conditions, but there is less evidence looking evidence in the healthcare worker population.

We set up a study under the Human Tissue Authority licence at the Nottingham Tissue Bank (PANTHER Tissue study) to allow healthcare workers (and their household contacts) to donate samples for testing for research purposes. As of June 2020, 640 participants have consented to donate tissue and over 3000 samples have been collected. This tissue will be subjected to antibody testing, and genetic sequencing to help understand the prevalence of COVID-19 in the healthcare worker population and genetic factors which influence COVID-19.

We would now like to contact participants to invite them to take part in a linked questionnaire study to enrich the human tissue authority study date by providing details about whether they experienced COVID-19 symptoms, their general health and wellbeing (including comorbidities), health related quality of life, and personal and occupational exposure along with questions related to their home circumstances.

Who can participate?

Healthcare workers and their household contacts who have donated blood to the Nottingham Tissue Bank for use in COVID research

What does the study involve?

Participants will complete sets of questionnaires at baseline and 12 weeks later.

What are the possible benefits and risks of participating?

None

Where is the study run from?

1. University of Nottingham (UK)
2. Nottingham University Hospitals (UK)

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

April 2020 to November 2021

Who is funding the study?

1. The Medical Research Council (UK)
2. UK Research and Innovation
3. Nottingham Biomedical Research Centre (UK)

Who is the main contact?

1. Jessica Nightingale, jessica.nightingale@nuh.nhs.uk.
2. Professor Ana Valdes, ana.valdes@nottingham.ac.uk
3. Professor Ben Ollivere, benjamin.ollivere@nottingham.ac.uk

Study website

<https://pantherstudy.org.uk/>

Contact information

Type(s)

Scientific

Contact name

Miss Jess Nightingale

Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

285436

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 47035, IRAS 285436

Study information

Scientific Title

PANdemic Tracking of HEalthcare woRKers Cohort and Questionnaire study

Acronym

PANTHER Cohort

Study objectives

Healthcare workers are more likely to develop COVID than non-healthcare workers. It is anticipated that certain characteristics (age, gender, ethnicity, occupational exposure) confer an increased risk of infection, and severe disease.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 27/10/2020 North West - Greater Manchester South Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8063; gmsouth.rec@hra.nhs.uk), ref: 20/NW/0395

Study design

Observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Internet/virtual

Study type(s)

Other

Participant information sheet

<https://pantherstudy.org.uk/participant-information/>

Health condition(s) or problem(s) studied

COVID-19 (SARS-CoV-2 infection)

Interventions

We set up a study under the Human Tissue Authority licence at the Nottingham Tissue Bank (Licence holder: Nottingham University Hospitals Trust, Licenced Tissue Bank (no. 11035)) to allow healthcare workers (and their household contacts) to donate blood samples for COVID research. We would now like to contact participants to invite them to take part in a linked questionnaire study to enrich the data collected under the human tissue authority licence by providing details about whether they experienced COVID symptoms, their general health and wellbeing (including comorbidities), health related quality of life, and personal and occupational exposure.

Participants will be asked to complete two questionnaires to provide health and wellbeing information. The first questionnaire will ask about their health and behaviour prior to lockdown and their health and behaviour during lockdown to the point of the first questionnaire. The second questionnaire will be sent at 12 weeks after recruitment and will ask participants to reflect on their health and behaviours in the previous 12 weeks. The questionnaire will ask the individual to provide details of their general health and wellbeing (including PHQ-9 and comorbidities), health related quality of life (EQ-5D-5L), and personal and occupational exposure (These questionnaires and questions are included in the questionnaire attached to the checklist). It will also ask individuals whether they have experienced COVID symptoms, had a positive COVID test or episodes of self-isolation. Participants will initially be sent the questionnaire by post. The postal communication will include a covering letter, participant information sheet, CRF and SAE. Individuals who fail to respond on the 1st attempt will be sent a reminder letter and second copy of the questionnaire.

Intervention Type

Other

Primary outcome measure

Health-related quality of life (EQ-5D) at baseline and 12 weeks

Secondary outcome measures

1. Development of COVID symptoms and antibodies during COVID pandemic, based on self-reporting and blood serology. This was measured during the first national lockdown, at the end of the first national lockdown, and in April 2021
2. Mood assessment measured using PHQ9 during the first national lockdown, at the end of the first national lockdown, and in April 2021

Overall study start date

01/04/2020

Completion date

01/11/2021

Eligibility

Key inclusion criteria

1. Healthcare workers and their household contacts who have donated blood to the Nottingham Tissue Bank for use in COVID research
2. Capacity to consent

3. Speak English
4. Minimum age 16 years, no upper age limit

Participant type(s)

Mixed

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 500; UK Sample Size: 500

Key exclusion criteria

Declined to be contacted for future research

Date of first enrolment

01/12/2020

Date of final enrolment

01/08/2021

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**Queen's Medical Centre**

Nottingham University Hospitals NHS Trust
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre**Nottingham University Hospital**

The Queen's Medical Centre Campus
Derby Road
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation

University of Nottingham

Sponsor details

Room East Atrium Jubilee Conference centre

Jubilee Campus

Nottingham

England

United Kingdom

NG8 1DH

+44(0)115 8467906

sponsor@nottingham.ac.uk

Sponsor type

University/education

Website

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

ROR

<https://ror.org/01ee9ar58>

Funder(s)

Funder type

Government

Funder Name

UK Research and Innovation; Grant Codes: MR/V027883/1

Alternative Name(s)

UKRI

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

Medical Research Council

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

Nottingham Biomedical Research Centre

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

01/11/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/02/2022	15/02/2022	Yes	No
HRA research summary			28/06/2023	No	No