The psychosocial impact of the COVID-19 pandemic on NHS affiliated staff – monitoring the response to the pandemic and the evaluation of local and national staff support programmes

Submission date 11/09/2020	Recruitment status No longer recruiting	[] Prospectively registered		
		[] Protocol		
Registration date 30/09/2020	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 30/08/2022	Condition category Mental and Behavioural Disorders	Individual participant data		

Plain English summary of protocol

Background and study aims

COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.

In 2020, the virus has spread to many countries around the world and neither a vaccine against the virus or specific treatment for COVID-19 has yet been developed. As of April 2020, it is advised that people minimize travel and social contact, and regularly wash their hands to reduce the spread of the virus.

Groups who are at a higher risk from infection with the virus, and therefore of developing COVID-19, include people aged over 70 years, people who have long-term health conditions (such as asthma or diabetes), people who have a weakened immune system and people who are pregnant. People in these groups, and people who might come into contact with them, can reduce this risk by following the up-to-date advice to reduce the spread of the virus. This study will investigate the impact of the COVID-19 pandemic on the psychological health and wellbeing of NHS staff in England.

Who can participate?

All staff working at or with a participating NHS Trust

What does the study involve?

A combination of online questionnaires and, with a smaller group of participants, more detailed telephone interviews. Participants will complete questionnaires about their health, distress, and work environment at the start of the study and 4 and 8 months later. The follow-up over time is

to see whether the participants' mental health improves or worsens and to identify which groups of staff may need tailored support. The questionnaire has been produced alongside healthcare staff in local NHS Trusts. The researchers have formed a study steering panel consisting of representatives whose support they have already gained (e.g., unions, employers, and different staff groups). They will feedback emerging results to participating Trusts, networks, their partners, and NHS England, from which they have full encouragement, to help them prepare for future psychological health and workforce planning needs.

What are the possible benefits and risks of participating?

Although there are no immediate individual benefits of taking part, participants will have the unique opportunity to contribute to some innovative and valuable research which may later be used across the world. Individuals may also find it helpful to reflect on the current situation and anonymously express their feelings concerning a stressful and unprecedented global event. The results will feed directly into supporting the NHS workforce during the pandemic. It is hoped that this research will help bring about improvements in policies and practices for NHS colleagues now and in the future. The researchers do not foresee any risks occurring from participation but if the questions lead to any distress they direct all participants who would like emotional support or find completing the survey causes distress to reach out to someone they trust. They also provide suggestions of outside support which can be accessed.

Where is the study run from?

This study is a collaborative effort led by a research team at King's College London and King's Health Partners supported by expert clinicians, frontline staff and researchers across different NHS Trusts and Universities, and the NIHR Maudsley Biomedical Research Centre (UK)

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

Who is funding the study?

- 1. King's College London (KCL) (UK)
- 2. NIHR Biomedical Research Centre at the Maudsley (UK)
- 3. Rosetrees Trust (UK)
- 4. University College London (UCL) (UK)
- 5. Medical Research Council (MRC) (UK)

Who is the main contact? Rupa Bhundia NHSCHECK@kcl.ac.uk

Study website https://www.nhscheck.org/

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number 282686

ClinicalTrials.gov number Nil known

Secondary identifying numbers IRAS 282686, CPMS 46176

Study information

Scientific Title

NHS CHECK: The psychosocial impact of the COVID-19 pandemic on NHS affiliated staff – monitoring the response to the pandemic and the evaluation of local and national staff support programmes

Acronym NHS CHECK

Study objectives

To establish a cohort of NHS-affiliated staff to investigate the short, medium- and longer-term psychosocial impact of the COVID-19 pandemic on staff performance and wellbeing.

Ethics approval required

Old ethics approval format

Ethics approval(s)

REC review not required as this study involves NHS staff Approved 24/04/2020, Health Research Authority (HRA) (address and tel not provided; approvals@hra.nhs.uk), ref: 20/HRA/2107

Study design Multicentre cohort study

Primary study design Observational

Secondary study design Cohort study

Study setting(s)

Hospital

Study type(s) Other

Participant information sheet https://www.nhscheck.org/CHECK_participant_information_sheet.pdf

Health condition(s) or problem(s) studied

The psychosocial impact of the COVID-19 pandemic on NHS affiliated staff – monitoring response to the pandemic and the evaluation of local and national staff support programmes

Interventions

Baseline online survey launched in April 2020 followed by repeated surveys at month 4, 8 and 12. The 4-month survey includes an evaluation of staff support programmes. A subset of participants will also be invited to participate in psychiatric diagnostic interviews between month 4 and month 8.

Intervention Type

Other

Primary outcome measure

General (non-psychotic) psychiatric morbidity, resilience, anxiety, depression, wellbeing, moral injury and burnout measured using online survey at baseline, month 4 and 12

Secondary outcome measures

Tiered and tailored staff support programmes being implemented locally and nationally, evaluated using online survey at month 4

Overall study start date

01/04/2020

Completion date

23/04/2022

Eligibility

Key inclusion criteria

1. Affiliated NHS member of staff, working at, or with, the participating NHS Trusts during the COVID-19 pandemic

- 2. Aged 18 and over
- 3. Able to give informed consent to take part in research
- 4. Able to understand and communicate in English
- 5. Have access to the internet to complete the surveys
- 6. Have access to an email address to facilitate survey registration and receive survey links

Participant type(s) Health professional

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

25% of the workforce at each participating sites, roughly 20,000

Key exclusion criteria

1. If participants are not an affiliated NHS member of staff, working at, or with, the participating NHS Trusts

2. Aged under 18

- 3. Unable to give informed consent to take part in research
- 4. Unable to understand and communicate in English
- 5. No access to the internet to complete the surveys
- 6. No access to an email address to facilitate survey registration and receive survey links

Date of first enrolment

24/04/2020

Date of final enrolment

23/04/2022

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Guy's and St Thomas' NHS Foundation Trust Westminster Bridge Rd London United Kingdom SE1 7EH

Study participating centre King's College Hospital Denmark Hill Brixton London United Kingdom SE5 9RS

Study participating centre South London and Maudsley NHS Foundation Trust Maudsley Hospital Denmark Hill London United Kingdom SE5 8AZ

Study participating centre Avon and Wiltshire Mental Health Partnership NHS Trust Avon and Wiltshire Mental Health Partnership NHS Trust Bristol United Kingdom BS16 2EW

Study participating centre Gloucestershire Hospitals NHS Foundation Trust United Kingdom GL1 2EL

Study participating centre

East Suffolk and North Essex NHS Foundation Trust Turner Rd Mile End Colchester United Kingdom CO4 5JL

Study participating centre

University Hospitals of Derby and Burton NHS Foundation Trust Uttoxeter Road Derby United Kingdom DE22 3NE

Study participating centre

Nottinghamshire Healthcare NHS Foundation Trust Duncan Macmillan House Porchester Road Nottingham United Kingdom NG3 6AA

Study participating centre

University Hospitals of Leicester NHS Foundation Trust Infirmary Square Leicester United Kingdom LE1 5WW

Study participating centre Cambridgeshire and Peterborough NHS Foundation Trust Cambridge United Kingdom CB21 5EF

Study participating centre Norfolk and Norwich University Hospitals NHS Foundation Trust Colney Lane Norwich United Kingdom NR4 7UY

Study participating centre Cambridge University Hospitals NHS Foundation Trust Hills Road Cambridge United Kingdom CB2 0QQ

Study participating centre Sheffield Health and Social Care Trust Fulwood House Old Fulwood Road Sheffield United Kingdom S10 3TH

Study participating centre Lancashire and South Cumbria NHS Foundation Trust Sceptre Point Sceptre Way Walton Summit Rd Walton Summit Centre Preston United Kingdom PR5 6AW

Study participating centre Tees Esk and Wear Valleys NHS Foundation Trust Middlesborough United Kingdom TS6 0SZ

Study participating centre Devon Partnership NHS Trust Wonford House Dryden Rd

Exeter United Kingdom EX2 5AF

Study participating centre Cornwall Partnership NHS Foundation Trust Carew House, Beacon Technology Park Dunmere Rd Bodmin Cornwall United Kingdom PL31 2QN

Study participating centre Royal Papworth Hospital NHS Foundation Trust Papworth Rd Trumpington Cambridge United Kingdom CB2 0AY

Sponsor information

Organisation King's College London

Sponsor details James Clerk Maxwell Building 57 Waterloo Road London England United Kingdom SE1 8WA -

R&D@gstt.nhs.uk

Sponsor type University/education

Website http://www.kcl.ac.uk/index.aspx

ROR

https://ror.org/0220mzb33

Funder(s)

Funder type Charity

Funder Name Rosetrees Trust

Alternative Name(s) Teresa Rosenbaum Golden Charitable Trust, Rosetrees

Funding Body Type Private sector organisation

Funding Body Subtype Trusts, charities, foundations (both public and private)

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 University College London

Alternative Name(s) University College London in United Kingdom, Collegium Universitatis Londinensis, UCL

Funding Body Type Government organisation

Funding Body Subtype Universities (academic only)

Location United Kingdom

Funder Name King's College London

Alternative Name(s) Collegium Regale Londiniense, King's, KCL

Funding Body Type Government organisation

Funding Body Subtype Universities (academic only)

Location United Kingdom

Funder Name NIHR Biomedical Research Centre at the Maudsley

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal. The researchers will feedback emerging results to participating Trusts, networks, their partners, and NHS England, from which they have full encouragement, to help them prepare for future psychological health and workforce planning needs. Additional documents are not currently available.

Intention to publish date

01/01/2021

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		Date created	Date added	Peer reviewed?	Patient- facing?
<u>Preprint</u> <u>results</u>	non-peer-reviewed baseline mental health survey results in preprint	22/01 /2021	19/03 /2021	No	No