Distress and resilience of healthcare professionals during the COVID-19 (coronavirus) pandemic

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
01/04/2020		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
01/04/2020	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
19/07/2022	Other			

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 March 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.

Despite containment measures, the virus spread exponentially. On March 11, 2020, the World Health Organization announced a pandemic. In Europe, the first clusters appeared on the 22nd of February 2020 in Northern Italy and soon the health system in Northern Italy could not cope with the massive amount of new patients with respiratory failure needing invasive ventilation support. The long-working hours, need for "hard triage" for ventilation support and the strong restrictions in daily life implemented by the government had serious effects on healthcare workers and the general population.

Front-line healthcare workers directly involved in the diagnosis, treatment and care of COVID-19 patients are despite getting infected and are under particular risk of developing psychological distress and other mental health symptoms. A recent study from China showed a high

prevalence of mental health symptoms among healthcare professionals, including depression, insomnia, anxiety or trauma stress disorder (Lai et al., 2020), similar to those found in military personnel after having been at war. Feelings of vulnerability to disease, concerns about spread of the virus to family members or friends, need for self-isolation and changes in the work sense of coherence are purported to play a role in the development of such symptoms. These negative stress outcomes can impact not only on the wellbeing of health professionals, but also on their ability to care effectively for others (Barnett, et al., 2007). Additionally, they affect all healthcare workers, irrespective of culture. On the other hand, individuals with a strong sense of coherence are less prone to burn-out and are mentally healthier. Moreover, adopting resilience-enhancing strategies may improve day-to-day performance at work and at home.

This study investigates the relationship between work sense of coherence and individual resilience on healthcare professionals' mental health during this COVID-19 pandemic. No other study addresses this gap in knowledge.

- 1. Is there a relationship between individual resilience and work sense of coherence and the development of anxiety, depression and traumatic stress disorder in frontline health care personnel during the pandemic outbreak?
- 2. Does contamination anxiety and COVID-19 anxiety differ over time, across countries in frontline health care personnel?
- 3. How does resilience and work sense of coherence influence the development of anxiety, depression and traumatic stress disorder in these health care workers during the pandemic outbreak?

Who can participate?

Healthcare professionals, >18 years of age, willing to participate.

What does the study involve?

Healthcare professionals will be asked to fill in a number of online questionnaires at three timepoints during a six-month period.

What are the possible benefits and risks of participating? None anticipated.

Where is the study run from?

Department of Anaesthesia and Pain Medicine, Inselspital, Bern University Hospital, Bern (Switzerland). Data will be collected from hospitals in Europe, USA, and New Zealand.

When is the study starting and how long is it expected to run for? April 2020 to May 2021 (updated 05/01/2021, previously: January 2021)

Who is funding the study?

Department of Anaesthesia and Pain Medicine, Inselspital, Bern University Hospital, Bern (Switzerland)

Who is the main contact?

Dr Alexander Fuchs, alexander.fuchs@insel.ch

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

DARVID1

Study information

Scientific Title

Distress And Resilience of healthcare professionals during the COVID-19 pandemic

Acronym

DARVID

Study objectives

- 1. COVID-19 anxiety and contamination anxiety do not remain stable over time, across countries, and relate to the proximity with infected patients.
- 2. There is a relationship between individual resilience and work sense of coherence and the development of mental symptoms in front liners during pandemic outbreaks

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 01/04/2020, Gesundheits- und Fürsorgedirektion des Kantons Bern, Kantonale Ethikkomission für die Forschung Bern (Ethics Committee of the Canton of Bern, Murtenstrasse 31, 3010 Bern, Switzerland; +41 31 633 7070; info.kek.kapa@gef.be.ch), ref: Req-2020-00355

Study design

Mixed-methods observational

Primary study design

Observational

Secondary study design

Qualitative research

Study setting(s)

Internet/virtual

Study type(s)

Other

Participant information sheet

https://psyunibe.qualtrics.com/jfe/form/SV_3WYgbkLWqiDPDG5

Health condition(s) or problem(s) studied

Individual resilience and work sense of coherence and the development of mental symptoms during a pandemic scenario

Interventions

Matched longitudinal internet-based survey with pre-existing, validated self-questionnaires (Work-SoC, PHQ-9, IES-6, PVD, SFI, CD-RISC 10), at 3 time periods of 2 weeks over 6 months, with the option to prolong depending on the development of the pandemic.

Semi-structured interviews with focus groups after the last period of the survey.

Intervention Type

Other

Primary outcome measure

COVID-19 Anxiety (adapted SARS-Anxiety-Scale) at 3 time periods of 2 weeks over 6 months

Secondary outcome measures

At 3 time periods of 2 weeks over 6 months:

- 1. Contamination anxiety (PVS)
- 2. Anxiety to get infected at work measured with a single generated Item («I am afraid I will become infected with COVID-19 while on the job») on a visual analog scale from «0 = Not at all» to «10 = Extremely»
- 3. Depression (PHQ-9)
- 4. Traumatic Stress (IES-6)
- 5. Work Coherence (Work-SoC)

Qualitative measures:

6. Influence of resilience and work sense of coherence on the development of anxiety, depression and trauma stress disorder in frontliners during pandemic outbreak measured using structured interview.

Overall study start date

15/03/2020

Completion date

01/05/2021

Eligibility

Key inclusion criteria

- 1. Healthcare professionals
- 2. >18 years of age
- 3. Willing to participate

Participant type(s)

Health professional

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

400

Total final enrolment

520

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

02/04/2020

Date of final enrolment

16/04/2020

Locations

Countries of recruitment

Australia

Austria
Belgium
Brazil
Bulgaria
Croatia
Cyprus
Czech Republic
Denmark
Finland
France
French Southern Territories
Germany
Greece
Ireland
Isle of Man
Israel
Italy
Lebanon
Liechtenstein
Lithuania
Luxembourg
Malta
Netherlands
New Zealand
Norway
Portugal

Slovakia Slovenia

South Africa

Spain

Sweden

Switzerland

Türkiye

United Kingdom

United States of America

Study participating centre Bern University Hospital

Department of Anaesthesiology and Pain Therapy Inselspital Freiburgstrasse 8-10 Bern Switzerland 3010

Sponsor information

Organisation

University Hospital of Bern

Sponsor details

Department of Anaesthesia and Pain Medicine Inelspital Freiburgstrasse 8-10 Bern Switzerland 3010 +41 31 632 88 35 robert.greif@insel.ch

Sponsor type

Hospital/treatment centre

Website

http://www.anaesthesiologie.insel.ch

ROR

https://ror.org/01q9sj412

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Hospital of Bern

Results and Publications

Publication and dissemination plan

Publication of results in the dedicated journals - first trimester 2021.

Intention to publish date

31/03/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Dr. Phil. Sandra Abegglen (sandra.abegglen@psy. unibe.ch). Both qualitative and quantitative data are expected to be available as from March 2021, for a period of 10 years. Data originating from questionnaires will be stored in a secure online site accessible to the investigators only. All researchers will comply with the Data Protection Act and the Swiss Law for Human Research. All data will be destroyed 10 years after the end of the project.

IPD sharing plan summary

Available on request

Study outputs

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Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>	protocol	31/07/2020	04/08/2020	Yes	No
Preprint results	psychological health results	07/06/2022	21/06/2022	No	No
Results article	Work-related sense of coherence results	16/05/2022	21/06/2022	Yes	No
Results article		30/06/2022	19/07/2022	Yes	No