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Distress and resilience of healthcare professionals during the COVID-19 pandemic (DARVID): study protocol for a mixed-methods research project

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Title Page

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Distress and resilience of healthcare professionals during the COVID-19 pandemic (DARVID): study protocol for a mixed-methods research project

Acronym: DARVID: **D**istress **a**nd **R**esilience of Healthcare Professionals during the CO**VID**-19 Pandemic

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Abstract

Introduction The unprecedented COVID-19 pandemic has exposed healthcare professionals to exceptional situations that can lead to increased anxiety (i.e., infection anxiety, perceived vulnerability), traumatic stress and depression. We will investigate the development of these psychological disturbances in healthcare professionals at the treatment front line and second line during the COVID-19 pandemic over a 12-month period in different countries. Additionally, we will explore whether personal resilience factors and a work-related sense of coherence influence the development of mental health problems of healthcare professionals.

Methods and analysis We plan to carry out a sequential qualitative–quantitative mixed-methods-design study. The quantitative phase consists of a longitudinal online survey based on six validated questionnaires, to be completed at three points in time. A qualitative analysis will follow at the end of the pandemic, to comprise at least nine semi-structured interviews. The *a-priori* sample size for the survey will be a minimum of 160 participants, which we will extend to 400, to compensate for drop-out. Recruitment into the study will be through personal invitations and the 'snowballing' sampling technique. Hierarchical linear regression combined with qualitative data analysis will facilitate greater understanding of any associations between resilience and mental health issues in healthcare professionals during pandemics.

Ethics and dissemination The study participants will provide their electronic informed consent. All recorded data will be stored on a secured research server at the study site, which will only be accessible to the investigators. The Bern Cantonal Ethics Committee has waived the need for ethical approval (Req-2020-00355; 1 April, 2020). There are no ethical, legal or security issues regarding the data collection, processing, storage and dissemination in this project.

Trial registration: ISRCTN13694948 (date of registration: 1 April, 2020)

Keywords: COVID-19, healthcare professionals, anxiety, resilience, distress, work-related sense of coherence, mental health, depression, trauma, front-liners; perceived vulnerability to disease

Strengths and limitations of this study

- The mixed-methods design with quantitative and qualitative phases that include several validated instruments and the matched follow-up and semi-structured interviews will provide substantial insight in the state and development of psychological health and the thoughts of healthcare professionals during infectious pandemics in several countries;
- The sophisticated statistical analysis will include a clustered hierarchical data structure and any imbalanced data, by allowing residual components at each level in the hierarchy;
- Interdisciplinary and interprofessional cooperation between physicians and health psychologists will combine different research approaches, and will therefore yield more holistic data by bridging disciplinary gaps;
- The participating healthcare professionals might not be representative of the entire population and for all countries;
- The survey will be accessible in English, to target a broad participation of international HCPs. This may limit participation and compliance of HCPs in regions where English is not common and introduce biases due to underrepresentation or misunderstandings.

Introduction

In December 2019, a new Coronavirus known as severe acute respiratory syndrome Coronavirus 2 (SARS CoV-2) appeared for the first time in Wuhan (China). SARS CoV-2 causes corona virus disease 2019 (COVID-19) which can lead to severe hypoxaemic pneumonia and other serious complications. Despite containment measures, the virus spread exponentially. The first case outside China was reported on the 13 January, 2020, in Thailand, which was connected to travel to Wuhan.[1] On 11 March, 2020, the World Health Organisation defined the COVID-19 outbreak as a pandemic.[2] In Europe, an Italian cluster developed exponentially, with the first deaths reported on 23 February, 2020.[3] It was soon clear that the health system in northern Italy could not cope with the large numbers of new patients with respiratory failure who required invasive ventilation support.[4] The COVID-19 pandemic put healthcare professionals (HCPs) in an unprecedented situation. The long working hours, the need for 'hard triage'[5 6] for ventilation support, and the tight restrictions on daily life implemented by the government had serious effects on both healthcare workers and the general population.[7]

Infectious diseases arise frequently, and nearly every year. However, these seldom challenge healthcare systems (e.g., limited capacity of hospital beds, understaffing of personnel) in the way seen for the COVID-19 pandemic. Therefore, data on the impact of such pandemics on HCPs are still not available.

A recent study from China showed a high prevalence of mental-health symptoms among all HCPs, including depression, insomnia, anxiety or trauma-stress disorder[8], similar to those experienced by military personnel after participation in war scenarios.[9] Front-line HCPs who are involved in diagnosis, treatment and care of COVID-19 patients[8] are at particular risk of developing psychological distress and other mental-health symptoms.[8 10] HCPs are expected to be under the highest perceived threat of COVID-19, and if they believe that their infection with COVID-19 is likely (i.e., perceived vulnerability), this might have serious consequences on their own health. Additionally, concerns about the spread of the virus to their family members or friends, their need for self-isolation, their feelings of not having enough support, and their exposure to the catastrophic news in the media are believed to have a role in the development of such symptoms.[8-11] These negative stress outcomes can impact not only on the wellbeing of HCPs, but also on their ability to care effectively for others.[12 13]

At the other end of the spectrum, people who have to endure significant challenges might experience a degree of post-traumatic growth[14], which is a term used to describe the strengthening of psychological resilience and values after exposure to particularly demanding situations.[15] Although there is as yet no universal definition, psychological resilience is generally considered to be multidimensional, and to consist of behaviours, thoughts and actions. In short, resilience refers to positive adaptation despite adversity.[16 17] Adopting resilience-enhancing strategies might therefore improve the day-to-day performance of HCPs at work.[18]

Personal resilience is also related to a sense of 'coherence'.[18 19] A sense of coherence is defined as a disposition to perceive life circumstances as manageable, comprehensible and meaningful. This might influence a person's resilience, by making them more adaptable in dealing with distress and adverse events.[18-21] People with a strong sense of coherence are less prone to *burn-out*, and are generally healthier.[13 22-25]

Due to the increasing prevalence of emerging infectious diseases (e.g., SARS CoV-1, Middle East respiratory syndrome [MERS] CoV) and other worldwide catastrophic events, the capacity to adapt is important, as it allows HCPs to act effectively and to stay healthy in potentially life-threatening situations.[18] More information about associations between resilience factors and a work-related sense of coherence of HCPs in such situations will help to counsel and support HCPs who are facing the consequences of 'COVID-19 anxiety', perceived vulnerability, hopelessness, depression and traumatic-stress symptoms.

This project is designed to primarily determine the degree of COVID-19 anxiety, perceived vulnerability, depression and traumatic-stress symptoms and their variation in HCPs for specific time periods and regions around the world. Additionally, the aim is to explore differences in COVID-19 anxiety, perceived vulnerability, depression and traumatic-stress symptoms between front-line (HCPs directly treating COVID-19 patients) and second-line (HCPs not involved in direct care of COVID-19 patients) HCPs. A third aim is to determine whether there are any associations between these factors and individual resilience and a work-related sense of coherence across the different phases of the COVID-19 pandemic.

Therefore, the research questions of this study are:

- Do COVID-19 anxiety and perceived vulnerability differ over time between different countries?

- Do COVID-19 anxiety and perceived vulnerability differ over time between first-line and second-line HCPs?
- How do individual resilience and a work-related sense of coherence influence the development of COVID-19 anxiety, perceived vulnerability, depression and traumatic-stress symptoms during the different phases of a pandemic outbreak?
- How do individual resilience and a work-related sense of coherence influence the development of COVID-19 anxiety, perceived vulnerability, depression and traumatic-stress symptoms of front-line HCPs?
- What factors contribute to or alleviate COVID-19 anxiety and perceived vulnerability over the study period for first-line HCPs?
- Which components of individual resilience and a work-related sense of coherence influence the development of COVID-19 anxiety, perceived vulnerability, depression and traumatic-stress symptoms during the study phases for front-line HCPs?

Methods and analysis

Study design overview

We will conduct a sequential mixed-methods study based on an explanatory design[26]. The first quantitative phase will explore the association of individual resilience, a work-related sense of coherence and the development of mental-health symptoms during the COVID-19 pandemic, and their variations over time, between countries and between front-line and second-line HCPs. The qualitative phase, collected and analysed after the quantitative phase, will consist of semi-structured interviews, and will elaborate on the development of mental health symptoms, use of coping strategies, and personal resilience factors during the COVID-19 pandemic in front-line HCPs. The combination of these two methodological approaches will allow triangulation and provide a more granular understanding of the processes involved in any associations with anxiety, perceived vulnerability, depression, traumatic-stress symptoms and resilience factors over the course of the current COVID-19 pandemic. The quantitative data and their subsequent analysis will provide a general understanding of the development of mental health symptoms during the pandemic, while the qualitative data and their analysis will refine and explain the statistical findings in more depth, by

exploring participants´ views, thoughts and feelings [27-29]. Data collection will be sequential (first quantitative and then qualitative) but both study parts will be given equal priority.

Quantitative phase: longitudinal online survey

Data collection

An online survey was launched on the 2 April, 2020, in English. This will collect data for 2 weeks. The follow-ups are planned for July and October 2020, over another 2-week period. Depending on the results of the follow-ups, a third might be added in late 2020.

The longitudinal internet-based survey is a 64-item questionnaire (Supplemental Digital Content 1) based on six pre-existing validated self-reporting questionnaires and demographic data. This questionnaire is hosted online at Qualtrics (Provo, Utah, USA), which restricts access to one response per device.

The survey link will be primarily distributed through social media (LinkedIn, Facebook, Twitter, WhatsApp, Threema), using the 'snowballing' sampling technique.[30-32] Later, personal contacts via e-mail invitations from all of the authors will invite further study participants, with supporting (inter)national societies e-mailing the link via their own mailing lists, to better distribute the survey. Contact persons are asked to further distribute the survey, to promote the greatest number of responses as possible over the entire study period.

To minimize the possibility of attrition bias we ensure a good communication between study coordinators and participants, send several personalized follow-up invitations, and apply oversampling technique[33]. Moreover, we contacted several healthcare professional associations and societies in different countries to ensure an HCP-oriented distribution of the survey and to minimize sample selectivity bias. We undertook a short pilot testing with the co-authors and some of the authors` colleagues.

Participant inclusion and exclusion criteria

We will include HCPs over 18 years of age who agree to participate. A HCP is defined as a postgraduate person listed in the sub-major group 22 (Health Professionals), according to the International Standard Classification of Occupations, with exclusion of minor group 225

(Veterinarians)[34]. This includes medical doctors, nursing and midwifery professionals, traditional and complementary medicine professionals, paramedical practitioners, dentists, pharmacists and environmental and occupational health and hygiene professionals. All participants who do not comply with these criteria will be excluded.

Measurements

The primary outcome of this study is the variation in COVID-19 anxiety in different regions, over three time periods, measured using a modified version of the Swine Flu Anxiety Items [SFI])[35] a 10-item survey developed to measure anxiety disorders and somatization (Cronbach's alpha = 0.85).

The secondary outcomes will include:

- the Perceived Vulnerability to Disease (PVD) questionnaire score,[36] a 15-item tool used to measure subjective vulnerability to disease (Cronbach's alpha = 0.82);
- the Patient Health Questionnaire (PHQ-9) score,[37] a 9-item tool developed for depression evaluation (Cronbach's alpha = 0.89);
- the Impact of Event Scale-6 (IES-6) score,[38] a 6-items tool for evaluation of symptoms of post-traumatic stress reactions (Cronbach's alpha = 0.80);
- the Connor-Davidson Resilience Scale (CD-RISC 10) score,[39] a 10-item tool, as a short version of the CD-RISC 25,[40] to evaluate individual resilience (Cronbach's alpha = 0.85);
- the Work-Sense of Coherence Scale (Work-SoC) score,[41] a 9-item tool to evaluate the perceived comprehensibility, manageability and meaningfulness of an individual's current work situation (Cronbach's alpha = 0.83);
- a globally measured current risk perception for becoming infected while working, as assessed by a self-created item "I am afraid I will become infected with COVID-19 while on the job" (measured on a visual analogue scale from 0-10);
- a globally measured current perception of the stress at work, as a second self-created item "How stressful is your current work situation for you?" (measured on a visual analogue scale from 0-10);
- socio-demographic variables, and work-related and COVID-19–related characteristics: country and city of current occupation, age, sex, profession, main working place, years working in the healthcare system, belonging to a risk population, sharing a household with other people, being

in a relationship, having children, being pregnant or living with a pregnant woman, private close contact with people belonging to the risk population, having had direct contact with COVID-19–infected patients, being infected with COVID-19, having been positively tested for COVID-19 antibodies.

Sample size calculation

The required sample size was calculated using an *a-priori* power analysis with G*Power 3.1.[42] Assuming a small effect size (f^2 = .15) for a repeated measure ANOVA with three time points and within-between interaction (α = .05, 1-β = .95), the minimum required sample size for four language groups was *n* = 160. To compensate for drop-out over the three measurement times, we will aim for 400 responders.

Statistical analysis plan

To accommodate between- and within-effects in light of possibly unequal numbers of observations, hierarchical linear mixed models will be fit to the longitudinal measures of the primary and secondary outcome variables.[43] Hierarchical linear regression accounts for non-independence of observations and attrition inherent in longitudinal data.[43] The analyses will be conducted using the R-package: nlme[44] in R Statistical Language,[45] using full maximum likelihood estimations. The normal distributions of the outcome variables will be examined by residual diagnostics of the fitted multilevel models.

For each primary and secondary outcome variable, the analysis will proceed according to different steps[43]. First, a null model (intercept only model) will be estimated, which allows an estimation of the proportion of variation in the outcome variables; i.e., between and within the persons in the sample. The first model (unconditional growth model with random intercept) will examine the within-persons trajectories of change across measurement points. The second model (conditional growth model with random intercept and cross-level interaction) will examine the effects of country/ front-line and second-line HCPs across the different times (i.e., the pandemic phase).

To address the research questions that are focussed on the relationships between the different outcome variables and the resilience and work-related sense of coherence, structural equation modelling will be performed[46]. These analyses will be carried out using the R-package: lavaan[47] in the R Statistical Language,[45] using full maximum likelihood estimation.

Statistical strategies for dealing with threats to internal validity (i.e. attrition bias, sample selectivity bias, multiple-testing bias) include extensive drop-out analyses[33], reporting of attrition by socioeconomic factors[33], statistical comparison of participants key characteristics with population characteristics, and applying of linear hierarchical regression analyses, which include all available data[41] and compensate for multiple testing[48].

Qualitative phase: semi-structured interviews

Data collection

After completion of the online survey, the participants will be invited to participate in the semi-structured interviews. We will select all of the participants for the qualitative phase according to availability and region. We will select them from the pool used in the quantitative phase, so as to best represent their experience and views. As the study is sequential in nature, it is impossible to pre-emptively select participants for the qualitative phase. Therefore, we will perform stratified purposive sampling into homogeneous focus groups, stratified by front- or second-liners, profession and country of origin, to enable comparisons[49 50]. We aim to perform at least nine semi-structured interview groups. All interviews will be coded in a phased fashion, with interim analysis to check for saturation (i.e., when additional data do not lead to any new themes). If saturation is not reached, three more interviews will be performed. Sixty-minute semi-structured interviews will be conducted after the quantitative phase is finished, in different locations in Europe. The aim is to explore participants' views on the influence of resilience and a work-related sense of coherence on the development of anxiety, depression and trauma-stress disorder during the pandemic outbreak. We used the protocol proposed by Castillo-Montoya[51] to develop a semi-structured interview guide (Supplemental Digital Content 2). We first ensured that interview questions were aligned with our research questions, we then constructed an inquiry-based conversation, we asked for external feedback on interview protocols and we will pilot the interview guide in the near future. The interview data will consist of the audio and video recordings, which will be further transcribed by two members of the study team.

Strategies for dealing with threats to validity of the qualitative data used in this study include method triangulation, member-checking (also known as participant validation)[52], peer support and an

audit trail. The use of triangulation of different data sources will enhance objectivity and strengthen intersubjective agreement[53]. A thorough methodologic description will also help credibility.

Analysis plan

All of the data will be processed with the software MaxQDA2020 (Verbi, Berlin, Germany). Data originating from the semi-structured interviews will be processed according to the Miles and Huberman[54] framework for data analysis. This initially includes data reduction – including segmenting, editing and summarising the data – followed by data display, and finally conclusions verification. Two investigators will code the first group interviews independently and will agree on the coding scheme for the remaining interviews. Respondent validation and paired coding will be performed as a way to increase quality. Memoing will be performed parallel to coding.

Trial status

The trial started to recruit participants for the first round of the survey (quantitative data) on 2 April, 2020, for a period of 2 weeks. The next rounds are planned for July and October 2020. After the quantitative data collection ends, we will move on to the qualitative phase.

Ethics and Dissemination

The Bern Cantonal Ethics Committee waived the need for ethical approval on 1 April, 2020, according to the Swiss Act for Human Research (BASEC Nr. 2020-00355, Prof. Dr. med Christian Seiler, Murtenstrasse 31, 3010 Bern, Switzerland, Tel: +41-31-6337070, info.kek.kapa@gef.be.ch). All procedures for this investigation will follow the Helsinki Declaration.[55]

All of the participants will be sent a link to the survey, with a detailed cover letter that explains the entire project, the purpose of the project, the context of the research, and the contacts of the lead investigator (available at https://psyunibe.qualtrics.com/jfe/form/SV_3WYgbkLWqiDPDG5). Electronic informed consent to participate will be obtained from all of the participants at the beginning of the survey. Should any participants decide not to participate in the study, their decision will not affect them in any way. No incentives will be offered or given. Participants will be asked for their e-mail, to enable contact with them during the follow-up and qualitative phases of the study, and for pairing

purposes. During the interviews, participants' faces will not be included in the video recordings, and their performances will not be shared with any external subjects.

All of the researchers involved will comply with the Data Protection Act and the Swiss Law for Human Research. There are no ethical, legal or security issues regarding the data collection, processing, storage and dissemination for this project. We will neither obtain nor generate sensitive data, and we do not sign any confidentiality agreement. All data will be stored for up to 10 years after the project, according to the Swiss Law for Human Research.

This study has been registered at the UK based International Standard Randomised Controlled Trial Number (ISRCTN) under the registration number: ISRCTN13694948. All relevant data generated or used by the research project (i.e., raw data, all processed data that directly underlies the reported results, and all ancillary information necessary to understand, evaluate, interpret and re-use the results of the study) will be stored on the official server of the Institute of Psychology, Department of Health Psychology and Behavioural Medicine at the University of Bern. All of the data are, and will be, password protected and only accessible by SA and HE. The datasets will be flagged for long-term storage. Datasets flagged for long-term storage are subjected to specific measures to preserve data integrity and data safety, such as additional back-ups, regular re-writes to new storage media, and redundant storage in third-party repositories.

The datasets generated and analysed during the current study will be available from the primary investigator upon reasonable request from university-based research groups with suitable and answerable research questions. The primary investigator will be responsible for ensuring that electronic file permissions are correctly assigned and for advising on other aspects of data storage and security. Both qualitative and quantitative data are expected to be available from March 2021. We expect no limitations with respect to publishing the data.

The study results will be published in a peer-reviewed international medical journal after the first trimester of 2021. A full timeline of the project is shown in Figure 1.

Public involvement statement

This research will be carried out without patient involvement, as patients are not the study subjects. We have involved the Swiss Association of Assistants and Registrars (VSAO), the Swiss Society of Anaesthesiology and Reanimation (SGAR) and the European Airway Management Society (EAMS) to

comment on the study design, and have consulted HCPs on relevant outcomes. After the data analysis, we will invite them to interpret the results again. We have not had time to invite persons outside the study group to contribute to the writing or editing of this document, because of the velocity of the progression of the COVID-19 pandemic.

Importance of the study

Despite the large body of literature that is focussed on the prevalence of mental health symptoms after catastrophes or natural disasters, the investigation of the resilience of HCPs is scarce, particularly in the face of a surge capacity. In disaster situations, the prevalence of resilience appears to depend on adequate preparedness, good social support and proactive coping styles[9]. However, most disaster sites do not impose social distancing and self-isolation procedures, which might further compromise the HCP ability to cope. It has been shown before that professionals involved in disaster relief work can develop post-traumatic growth[14 15]. Establishing a clear relationship between resilience and a work-related sense of coherence with the development of mental symptoms during exceptional situations like the current COVID-19 pandemic might help to identify HCPs who are both particularly protected and at risk, which will allow the adequate distribution of psychological interventions. Organisations can also potentiate resilience in their employees by ensuring that they are adequately trained. This is would be an affordable measure that can save money and resources by keeping the staff at work and avoiding sick leave.

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Competing interest statement: The authors have no competing interests to declare

Figure Legend:

Figure 1: Project timeline

Additional Files

Supplemental Digital Content 1 – Online Questionnaire

Supplemental Digital Content 2 – DARVID guidance document for the interviews

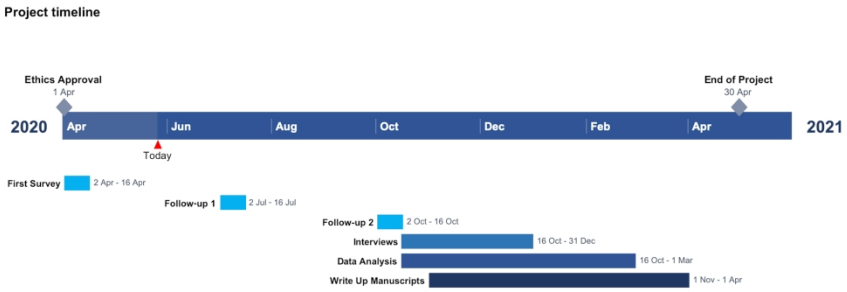

Figure 1: Project timeline

297x209mm (300 x 300 DPI)

COVID-19

Start of Block: Block 1

Q23

Distress and Resilience of Healthcare Professionals during the COVID-19-Pandemic (DARVID): An observational longitudinal questionnaire trial We invite you to participate in our 9-month study on the association of psychological distress and coping strategies of healthcare professionals during the current COVID-19-pandemic in Europe.

Healthcare professionals who participate in this study will help to gain a better understanding of work-related distress, psychological health and resilience factors in the current pandemic outbreak. These results will serve to develop specific interventions to foster the individual and organizational resilience of medical healthcare providers in the future. This is why your contribution is very important.
When you enter the survey, you will be asked to complete questionnaires. This will take between 10 to 15 minutes.

Most of these questionnaires have already been validated. We could not modify questions, thus some statements might sound strange in the current situation. Please answer as accurately as possible. As per study design, it will not be possible to skip questions. We need to collect all the information.

Your participation in this study is voluntary. If you decide at any time not to participate, it will not affect the care, services or benefits to which you are entitled. Answering these questions has no known risks for you. If you interrupt in the answering process you may return later as your answers are temporarily saved for 7 days after your last activity.
All information taken from the study will be coded for analysis to protect each subject's identity. However, we will need your e-mail for further contact. We expect to repeat the survey in the summer and autumn. No identifying information will be used when discussing or reporting data. The investigators will keep all files and data collected safely at the departmental research server according to the Swiss law on human research. Once all data has been fully analyzed it will be kept for 10 years according to local research law.
The Bern Cantonal Ethics Committee has waived the need for ethical approval.

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Q23 I have read the foregoing information. I consent voluntarily to participate in this study.

- Yes (1)
- No (2)

End of Block: Block 1

Start of Block: Block 13

Q28 All information taken from the study will be coded to protect each subject's name. The study group needs your e-mail to contact you for the summer and fall questionnaires, but never ever identifying information will be used when discusssing or reporting data and results of the study.

Q29 Your e-mail address

_____

Q30 The investigators will safely keep password protected all files and data safe at the departmental research server according to the Swiss law on human research. Once all data has been fully analyzed it will be kept for 10 years according to local research law.

End of Block: Block 13

Start of Block: Block 2

Q34 In which country do you currently work?

▼ Afghanistan (1) ... Zimbabwe (1357)

Q32 In which city do you currently work?

_____

*

Q2 Age in years:

_____

Q3 Your gender?

- Male (1)
- Female (2)
- Other (3)

End of Block: Block 2

Start of Block: Block 12

Q27
We need an informed consent from you. Otherwise you cannot participate.

Your decision to participate in this study is complete voluntary. If you decide to not participate, it will not affect the care, services, or benefits to which you are entitled.

If you decide to participate in this study, please go back and indicate "yes".

End of Block: Block 12

Start of Block: Block 3

Q11 What is your profession?

- Nurse (1)
- Physician (2)
- Midwife (3)
- Pre-hospital Technician (4)
- Other (what?) (5) _____

Q33 Your main working place is:

- ICU (1)
- Anesthesia/Surgery (2)
- Emergency room (3)
- Ward (4)
- Other (where?) (5) _____

Q12 Have you had direct contact (i.e. diagnosed, treated or provided care) with COVID-19 infected patients?

- Yes (1)
- No (2)

*

Q10 How many years are you working in the healthcare system, since graduation?

_____

Q13 Do you belong to a risk population? (i.e. Over the Age of 65 years, High blood pressure, Diabetes, Cardiovascular disease, Chronic respiratory diseases, Conditions and therapies that weaken the immune system, Cancer)

- Yes (1)
- No (2)

End of Block: Block 3

Start of Block: Block 4

Q8 Do you share your household with other people?

- Yes (1)
- No (2)

Q4 Are you in a relationship?

- Yes (1)
- No (2)

Q5 Do you have children?

- Yes (1)
- No (2)

Q15 Are you pregnant or are you living together with a pregnant woman?

- Yes (1)
- No (2)

Q14 Do you have close contact in private to people of the risk population mentioned above?

- Yes (1)
- No (2)

End of Block: Block 4

Start of Block: Block 14

Q33 Are you infected with COVID-19?

- Yes (1)
- No (2)
- Don't know (4)

Q34 Have you been positively tested for COVID-19 antibodies?

- Yes (1)
- No (2)

End of Block: Block 14

Start of Block: Block 5

Q17 Below is a list of statement about concerns with respect to COVID-19 (SFI Questionnaire). Please indicate how much you agree with each statement.

	very little (1)	(2)	(3)	(4)	very much (5)
To what extent are you concerned about COVID-19? (1)	○	○	○	○	○
To what extent do you believe that COVID-19 could become a "pandemic" in you current resident country? (2)	○	○	○	○	○
How likely is it that you could become infected with COVID-19? (3)	○	○	○	○	○
How likely is it that someone you know could become infected with COVID-19? (4)	○	○	○	○	○
How quickly do you believe contamination from COVID-19 is spreading in your current resident country? (5)	○	○	○	○	○
How much exposure have you had	○	○	○	○	○

to information about COVID-19? (6)					
If you did become infected with COVID-19, to what extent are you concerned that you will be severly ill? (7)					
To what extend has the threat of COVID-19 influenced your decisions to be around people? (8)					
To what extend has the threat of COVID-19 influenced your travel plans? (9)					
To what extend has the threat of COVID-19 influenced your use of safety behaviors (e.g. hand sanitizer)? (10)					

End of Block: Block 5

Start of Block: Block 6

Q21 Over **the last 2 weeks**, how often have you been bothered by any of the following problems?
(PHQ-9 Questionnaire)

	Not at all (1)	Several days (2)	More than half the days (3)	Nearly every day (4)
Little interest or pleasure in doing things (1)	○	○	○	○
Feeling down, depressed, or hopeless (2)	○	○	○	○
Trouble falling or staying asleep, or sleeping too much (3)	○	○	○	○
Feeling tired or having little energy (4)	○	○	○	○
Poor appetite or overeating (5)	○	○	○	○
Feeling bad about yourself - or that you are a failure or have let yourself or your familiy down (6)	○	○	○	○
Trouble concentrating on things, such as reading the newspaper or watching television (7)	○	○	○	○
Moving or speaking so slowly that other people could have noticed? Or the opposite - being so fidgety or restless that you have been moving around a	○	○	○	○

lot more than usual (8)				
Thoughts that you would be better off dead or of hurting yourself in some way (9)	○	○	○	○

End of Block: Block 6

Start of Block: Block 7

Q24 .

	0 (Not at all)	10 (Extremely)
I am afraid I will become infected with COVID-19 while on the job. ()		

Q25 .

	0 (Not at all)	10 (Extremely)
How stressful is your current work situation for you? ()		

End of Block: Block 7

Start of Block: Block 8

Q19

Please read each statement below, and indicate how distressing each difficulty has been for you during the **past 7 days** with respect to **your current work situation**. How much have you been distressed or bothered by these difficulties? (IES-6-questionnaire)

	Not at all (1)	A little bit (2)	Moderately (3)	Quite a bit (4)	Extremely (5)
I thought about it when I didn't mean to. (1)	○	○	○	○	○
I felt watchful or on-guard. (2)	○	○	○	○	○
Other things kept making me think about it. (3)	○	○	○	○	○
I was aware that I still had a lot of feelings about it, but I didn't deal with them. (4)	○	○	○	○	○
I tried not to think about it. (5)	○	○	○	○	○
I had trouble concentrating. (6)	○	○	○	○	○

End of Block: Block 8

Start of Block: Block 9

Q25 How do you personally find your current job and work situation in general?

	1 (1)	2 (2)	3 (3)	4 (4)	5 (5)	6 (6)	7 (7)	
manageable	○	○	○	○	○	○	○	unmanageable
meaningless	○	○	○	○	○	○	○	meaningful
structured	○	○	○	○	○	○	○	unstructured
easy to influence	○	○	○	○	○	○	○	impossible to influence
insignificant	○	○	○	○	○	○	○	significant
clear	○	○	○	○	○	○	○	unclear
controllable	○	○	○	○	○	○	○	uncontrollable
unrewarding	○	○	○	○	○	○	○	rewarding
predictable	○	○	○	○	○	○	○	unpredictable

End of Block: Block 9

Start of Block: Block 10

Q22

For each statement below, please make one selection that best indicates how much you agree with the following statements as they apply to you over the **last 4 weeks.** (CD-RISC Questionnaire)

If a particular situation has not occurred recently, answer according to how you think you would have felt.

	not true at all (1)	rarely true (2)	sometimes true (3)	often true (4)	true nearly all of the time (5)
I am able to adapt when changes occur. (1)	○	○	○	○	○
I can deal with whatever comes my way. (2)	○	○	○	○	○
I try to see the humorous side of things when I am faced with problems. (3)	○	○	○	○	○
Having to cope with stress can make me stronger. (4)	○	○	○	○	○
I tend to bounce back after illness, injury, or other hardships. (5)	○	○	○	○	○
I believe I can achieve my goals, even if there are obstacles. (6)	○	○	○	○	○
Under pressure, I stay focused and think clearly. (7)	○	○	○	○	○

I am not easily discouraged by failure. (8)	○	○	○	○	○
I think of myself as a strong person when dealing with life's challenges and difficulties (9)	○	○	○	○	○
I am able to handle unpleasant or painful feelings like sadness, fear, and anger. (10)	○	○	○	○	○

End of Block: Block 10

Start of Block: Default Question Block

Q16 Finally, please indicate how much you agree at present with each statement. (PVD Questionnaire)

	strongly disagree (1)	(2)	(3)	(4)	(5)	(6)	strongly agree (7)
In general, I am very susceptible to colds, flu and other infectious diseases. (1)	○	○	○	○	○	○	○
I am unlikely to catch a cold, flu or other illness, even if it's "going around". (2)	○	○	○	○	○	○	○
If an illness is "going aroud", i will get it. (3)	○	○	○	○	○	○	○
My immune system protects me from most illnesses that other people get. (4)	○	○	○	○	○	○	○
I am more likely than the people around me to catch an infectious disease. (5)	○	○	○	○	○	○	○
My past experiences make me believe I am not likely to get sick even when	○	○	○	○	○	○	○

my friends are sick. (6)							
I have a history of susceptibility to infectious disease. (7)							
I prefer to wash my hands pretty soon after shaking someone's hand. (8)							
I avoid using public telephones because of the risk that i may catch something from the previous user. (9)							
I do not like to write with a pencil someone else has obviously chewed on. (10)							
I dislike wearing used clothes because you do not know what the last person who wore it was like. (11)							
I am comfortable sharing a water bottle with a friend.							

(12) It really bothers me when people sneeze without covering their mouths. (13)	○	○	○	○	○	○	○
It does not make me anxious to be around sick people. (14)	○	○	○	○	○	○	○
My hands do not feel dirty after touching money. (15)	○	○	○	○	○	○	○

End of Block: Default Question Block

Start of Block: Block 11

Q32 Do you have any comments or suggestions?

_____

_____

_____

_____

_____

End of Block: Block 11

Last page:

You have now completed the full questionnaire – Thank you!

Your contribution in this study is of utmost importance to gain insight on healthcare providers´ resilience in the present time.

We will ask you to fill in another shorter questionnaire in summer and in autumn.

Kind regards,

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Interview Guide for Semi-Structured Interviews: Distress and Resilience of Healthcare Professionals during the COVID-19-Pandemic (DARVID)

Before we begin:

1. Extend your greetings, and thank all of the participants for being there and for their participation. Remind them that the interview will be video and audio recorded, and then viewed by the investigating team, for coding and transcription purposes. Tell them that you guarantee that all information will remain anonymous.
2. Ask for their written voluntary consent to participate in the interview.
3. Explain that, first and foremost, our interest in the focus group is to evaluate the ideas of the participants and their contributions.
4. Set the ground rules for group discussion (i.e., role of facilitators, role of the assistant, audio and video recording, raising hands, do not speak at the same time).
5. ***Start the video and audio-recording devices***

Introduction (5 minutes)

1. Explanation that the focus group will be divided into different sections.
2. Short presentation round.
3. Experience and background of participants:

- Age (Make a note on sex)
- Profession/ in the front line?
- Previous work experience

4. Were you working in your usual workplace during the pandemic? If not, where?
5. Ask about the experience of filling in the questionnaire, and what the participants thought was the purpose of it.

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Survey (45 minutes)

1. *Explain briefly the purpose of the study (association of resilience and a work-related sense of coherence with development of mental health symptoms).*

Stress / Personal circumstances

2. What was the most relevant stress factor related to work and to private life during the pandemic?

Perceived vulnerability

3. Were you especially afraid of being contaminated? When?
4. What did you do to manage your worries about contamination?

Traumatic stress

5. How was your sleeping quality and quantity during the special situation of the COVID-19 pandemic compared to before the pandemic arrived?
    a. Did you have nightmares during the COVID-19 pandemic, or do you at present?
    b. Did you have difficulties falling asleep during the COVID-19 pandemic, or do you at present?
    c. Did you have difficulties staying asleep for several hours?
6. If you remember your working situation during the COVID-19 pandemic: Were you exposed to a very stressful event that was life-threating for you or another person, which was frightening or distressing for you during the COVID-19 pandemic? (If you feel ok to describe this event a little bit more, please do it)
    a. What do you do if distressing and intense memories come up?
    b. Do you experience physical reactions or severe distress when you are reminded or relating to this event / or your working situation during the COVID-19 pandemic? (Which?)

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c. What do you do if physical reactions or severe distress come up?

7. Did you notice any difference in your emotional state during the COVID-19 pandemic (i.e. feeling more aggressive, feeling numb, being hypervigilant, feeling guilty)?

Depression

8. The following questions will focus on your state of depression related to your working situation during the COVID-19 pandemic
    a. Have you felt depressed? In which situation?
    b. What have you done to feel more comfortable?
9. Did you experience appetite disorders (poor appetite/ overeating), panic attacks, worry all the time, etc?

Resilience

10. What do you think resilience is?
    a. Did you feel especially resilient during the pandemic?
    b. What was the most important individual factor and social factor that improved your resilience during the pandemic?
    c. What would be helpful for you to enhance your resilience at work in the future?
    d. What can your organisation do to enhance your resilience at work in the future?

Work-related sense of coherence

11. When you think about your working situation during the COVID-19 pandemic, what was different during the pandemic?
12. What was it like to provide care for COVID-19 patients?
13. How do you feel your hospital performed during the pandemic?

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Final remarks (5 minutes)

1. If you advise your past self (six months ago) on how to react to the Corona pandemic, what would your main advice be?
2. Thank you (distribution of an incentive voucher?)
3. ***Stop video and audio-recording devices***

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym → **page 1**
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry → **page 2**
	2b	All items from the World Health Organization Trial Registration Data Set → **n/a**
Protocol version	3	Date and version identifier → **page 1**
Funding	4	Sources and types of financial, material, and other support → **page 19**
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors → **page 1**
	5b	Name and contact information for the trial sponsor → **n/a**
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities→ **n/a**
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) → **n/a**
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention → **page 4-6**
	6b	Explanation for choice of comparators→ **n/a**
Objectives	7	Specific objectives or hypotheses → **page 4-6**

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) → **page 6**
Methods: Participants, interventions, and outcomes		
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained → **page 6-7,10**
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) → **page 7-8**
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered → **n/a (observational study)**
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) → **n/a (observational study)**
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) → **n/a (observational study)**
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial → **n/a (observational study)**
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended → **page 8-10 (quantitative phase) & 10-11 (qualitative phase)**
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) → **page 19, Figure 1**
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations → **page 9 (quantitative phase) & page 10 (qualitative phase)**
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size → **page 7**
Methods: Assignment of interventions (for controlled trials) → **n/a (observational study)**		

Allocation:		
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions → **n/a (observational study)**
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned → **n/a (observational study)**
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions → **n/a (observational study)**
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how → **n/a (observational study)**
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial → **n/a (observational study)**
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol → **page 7-9 (quantitative phase) & page 10-11 (qualitative phase)**
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols → **n/a**
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol → **page 12**
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol → **page 8-9 (quantitative phase) & page 11 (qualitative phase)**

	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) → **n/a**
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) → **n/a**
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed → **page 12**
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial → **n/a**
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct → **n/a**
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor → **n/a**
Ethics and dissemination		
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval → **page 11-12**
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) → **n/a**
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) → **page 11-12**
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable → **n/a**
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial → **page 11-12**
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site → **page 19**

Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators → **page 11-12**
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation → **n/a**
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions → **page 12-13**
	31b	Authorship eligibility guidelines and any intended use of professional writers → **page 19**
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code → **page 11-12**
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates → **page 11-12 & SDC1, page 1**
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable → **n/a**

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.