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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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Fuchs, Alexander Fabian

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3 1 Title Page

4
5 2 **Scientific title:**

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7 3 **Distress and resilience of healthcare professionals during the COVID-19 pandemic (DARVID):**
8
9 4 **study protocol for a mixed-methods research project**

10
11 5
12 6 **Acronym:** DARVID: **D**istress and **R**esilience of Healthcare Professionals during the **COVID-19**
13
14 7 Pandemic

15
16 8
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1
2
3 **25 Abstract**
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5 **26**

7 **27 Introduction** The unprecedented COVID-19 pandemic has exposed healthcare professionals to
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9 **28** exceptional situations that can lead to increased anxiety (i.e., infection anxiety, perceived
10
11 **29** vulnerability), traumatic stress and depression. We will investigate the development of these
12
13 **30** psychological disturbances in healthcare professionals at the treatment front line and second line
14
15 **31** during the COVID-19 pandemic over a 12-month period in different countries. Additionally, we will
16
17 **32** explore whether personal resilience factors and a work-related sense of coherence influence the
18
19 **33** development of mental health problems of healthcare professionals.

20 **34 Methods and analysis** We plan to carry out a sequential qualitative–quantitative mixed-methods-
21
22 **35** design study. The quantitative phase consists of a longitudinal online survey based on six validated
23
24 **36** questionnaires, to be completed at three points in time. A qualitative analysis will follow at the end of
25
26 **37** the pandemic, to comprise at least nine semi-structured interviews. The *a-priori* sample size for the
27
28 **38** survey will be a minimum of 160 participants, which we will extend to 400, to compensate for drop-
29
30 **39** out. Recruitment into the study will be through personal invitations and the ‘snowballing’ sampling
31
32 **40** technique. Hierarchical linear regression combined with qualitative data analysis will facilitate greater
33
34 **41** understanding of any associations between resilience and mental health issues in healthcare
35
36 **42** professionals during pandemics.

37 **43 Ethics and dissemination** The study participants will provide their electronic informed consent. All
38
39 **44** recorded data will be stored on a secured research server at the study site, which will only be
40
41 **45** accessible to the investigators. The Bern Cantonal Ethics Committee has waived the need for ethical
42
43 **46** approval (Req-2020-00355; 1 April, 2020). There are no ethical, legal or security issues regarding the
44
45 **47** data collection, processing, storage and dissemination in this project.

46
47 **48** Trial registration: ISRCTN13694948 (date of registration: 1 April, 2020)
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49 **49**
50
51 **50**

52
53 **51 Keywords:** COVID-19, healthcare professionals, anxiety, resilience, distress, work-related sense of
54
55 **52** coherence, mental health, depression, trauma, front-liners; perceived vulnerability to disease
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57 **53**
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60

54 **Strengths and limitations of this study**

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

69 Introduction

70

71 In December 2019, a new Coronavirus known as severe acute respiratory syndrome Coronavirus 2
72 (SARS CoV-2) appeared for the first time in Wuhan (China). SARS CoV-2 causes corona virus
73 disease 2019 (COVID-19) which can lead to severe hypoxaemic pneumonia and other serious
74 complications. Despite containment measures, the virus spread exponentially. The first case outside
75 China was reported on the 13 January, 2020, in Thailand, which was connected to travel to Wuhan.¹
76 On 11 March, 2020, the World Health Organisation defined the COVID-19 outbreak as a pandemic.²
77 In Europe, an Italian cluster developed exponentially, with the first deaths reported on 23 February,
78 2020.³ It was soon clear that the health system in northern Italy could not cope with the large numbers
79 of new patients with respiratory failure who required invasive ventilation support.⁴ The COVID-19
80 pandemic put healthcare professionals (HCPs) in an unprecedented situation. The long working
81 hours, the need for 'hard triage'^{5 6} for ventilation support, and the tight restrictions on daily life
82 implemented by the government had serious effects on both healthcare workers and the general
83 population.⁷

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

88 A recent study from China showed a high prevalence of mental-health symptoms among all
89 HCPs, including depression, insomnia, anxiety or trauma-stress disorder⁸, similar to those
90 experienced by military personnel after participation in war scenarios.⁹ Front-line HCPs who are
91 involved in diagnosis, treatment and care of COVID-19 patients⁸ are at particular risk of developing
92 psychological distress and other mental-health symptoms.^{8 10} HCPs are expected to be under the
93 highest perceived threat of COVID-19, and if they believe that their infection with COVID-19 is likely
94 (i.e., perceived vulnerability), this might have serious consequences on their own health. Additionally,
95 concerns about the spread of the virus to their family members or friends, their need for self-isolation,
96 their feelings of not having enough support, and their exposure to the catastrophic news in the media
97 are believed to have a role in the development of such symptoms.⁸⁻¹¹ These negative stress outcomes
98 can impact not only on the wellbeing of HCPs, but also on their ability to care effectively for others.^{12 13}

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3 99 At the other end of the spectrum, people who have to endure significant challenges might
4
5 100 experience a degree of post-traumatic growth¹⁴, which is a term used to describe the strengthening of
6
7 101 psychological resilience and values after exposure to particularly demanding situations.¹⁵ Although
8
9 102 there is as yet no universal definition, psychological resilience is generally considered to be
10
11 103 multidimensional, and to consist of behaviours, thoughts and actions. In short, resilience refers to
12
13 104 positive adaptation despite adversity.^{16 17} Adopting resilience-enhancing strategies might therefore
14
15 105 improve the day-to-day performance of HCPs at work.¹⁸

16 106 Personal resilience is also related to a sense of ‘coherence’.^{18 19} A sense of coherence is
17
18 107 defined as a disposition to perceive life circumstances as manageable, comprehensible and
19
20 108 meaningful. This might influence a person’s resilience, by making them more adaptable in dealing
21
22 109 with distress and adverse events.¹⁸⁻²¹ People with a strong sense of coherence are less prone to
23
24 110 *burn-out*, and are generally healthier.^{13 22-25}

26 111 Due to the increasing prevalence of emerging infectious diseases (e.g., SARS CoV-1, Middle
27
28 112 East respiratory syndrome [MERS] CoV) and other worldwide catastrophic events, the capacity to
29
30 113 adapt is important, as it allows HCPs to act effectively and to stay healthy in potentially life-
31
32 114 threatening situations.¹⁸ More information about associations between resilience factors and a work-
33
34 115 related sense of coherence of HCPs in such situations will help to counsel and support HCPs who are
35
36 116 facing the consequences of ‘COVID-19 anxiety’, perceived vulnerability, hopelessness, depression
37
38 117 and traumatic-stress symptoms.

39 118 This project is designed to primarily determine the degree of COVID-19 anxiety, perceived
40
41 119 vulnerability, depression and traumatic-stress symptoms and their variation in HCPs for specific time
42
43 120 periods and regions around the world. Additionally, the aim is to explore differences in COVID-19
44
45 121 anxiety, perceived vulnerability, depression and traumatic-stress symptoms between front-line (HCPs
46
47 122 directly treating COVID-19 patients) and second-line (HCPs not involved in direct care of COVID-19
48
49 123 patients) HCPs. A third aim is to determine whether there are any associations between these factors
50
51 124 and individual resilience and a work-related sense of coherence across the different phases of the
52
53 125 COVID-19 pandemic.

54
55 126 Therefore, the research questions of this study are:

- 56
57 127 • Do COVID-19 anxiety and perceived vulnerability differ over time between different countries?
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3 128 • Do COVID-19 anxiety and perceived vulnerability differ over time between first-line and second-
4
5 129 line HCPs?
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7 130 • How do individual resilience and a work-related sense of coherence influence the development
8
9 131 of COVID-19 anxiety, perceived vulnerability, depression and traumatic-stress symptoms
10
11 132 during the different phases of a pandemic outbreak?
12
13 133 • How do individual resilience and a work-related sense of coherence influence the development
14
15 134 of COVID-19 anxiety, perceived vulnerability, depression and traumatic-stress symptoms of
16
17 135 front-line HCPs?
18
19 136 • What factors contribute to or alleviate COVID-19 anxiety and perceived vulnerability over the
20
21 137 study period for first-line HCPs?
22
23 138 • Which components of individual resilience and a work-related sense of coherence influence the
24
25 139 development of COVID-19 anxiety, perceived vulnerability, depression and traumatic-stress
26
27 140 symptoms during the study phases for front-line HCPs?
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29 141

30 142 **Methods and analysis**

31 143

32 144 ***Study design overview***

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36 145 We will conduct a sequential mixed-methods study based on an explanatory design²⁶. The first
37
38 146 quantitative phase will explore the association of individual resilience, a work-related sense of
39
40 147 coherence and the development of mental-health symptoms during the COVID-19 pandemic, and
41
42 148 their variations over time, between countries and between front-line and second-line HCPs. The
43
44 149 qualitative phase, collected and analysed after the quantitative phase, will consist of semi-structured
45
46 150 interviews, and will elaborate on the development of mental health symptoms, use of coping
47
48 151 strategies, and personal resilience factors during the COVID-19 pandemic in front-line HCPs. The
49
50 152 combination of these two methodological approaches will allow triangulation and provide a more
51
52 153 granular understanding of the processes involved in any associations with anxiety, perceived
53
54 154 vulnerability, depression, traumatic-stress symptoms and resilience factors over the course of the
55
56 155 current COVID-19 pandemic. The quantitative data and their subsequent analysis will provide a
57
58 156 general understanding of the development of mental health symptoms during the pandemic, while the
59
60 157 qualitative data and their analysis will refine and explain the statistical findings in more depth, by

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3 158 exploring participants' views, thoughts and feelings²⁷⁻²⁹. Data collection will be sequential (first
4
5 159 quantitative and then qualitative) but both study parts will be given equal priority.
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9 161 ***Quantitative phase: longitudinal online survey***

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13 163 *Data collection*

14 164 An online survey was launched on the 2 April, 2020, in English. This will collect data for 2 weeks. The
15
16 165 follow-ups are planned for July and October 2020, over another 2-week period. Depending on the
17
18 166 results of the follow-ups, a third might be added in late 2020.
19

20 167 The longitudinal internet-based survey is a 64-item questionnaire (Supplemental Digital
21
22 168 Content 1) based on six pre-existing validated self-reporting questionnaires and demographic data.
23
24 169 This questionnaire is hosted online at Qualtrics (Provo, Utah, USA), which restricts access to one
25
26 170 response per device.
27

28 171 The survey link will be primarily distributed through social media (LinkedIn, Facebook, Twitter,
29
30 172 WhatsApp, Threema), using the 'snowballing' sampling technique.³⁰⁻³² Later, personal contacts via e-
31
32 173 mail invitations from all of the authors will invite further study participants, with supporting
33
34 174 (inter)national societies e-mailing the link via their own mailing lists, to better distribute the survey.
35
36 175 Contact persons are asked to further distribute the survey, to promote the greatest number of
37
38 176 responses as possible over the entire study period.
39

40 177 To minimize the possibility of attrition bias we ensure a good communication between study
41
42 178 coordinators and participants, send several personalized follow-up invitations, and apply
43
44 179 oversampling technique³³. Moreover, we contacted several healthcare professional associations and
45
46 180 societies in different countries to ensure an HCP-oriented distribution of the survey and to minimize
47
48 181 sample selectivity bias. We undertook a short pilot testing with the co-authors and some of the
49
50 182 authors' colleagues.
51

52 183

53 184 *Participant inclusion and exclusion criteria*

54
55 185 We will include HCPs over 18 years of age who agree to participate. A HCP is defined as a
56
57 186 postgraduate person listed in the sub-major group 22 (Health Professionals), according to the
58
59 187 International Standard Classification of Occupations, with exclusion of minor group 225
60

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3 188 (Veterinarians)³⁴. This includes medical doctors, nursing and midwifery professionals, traditional and
4
5 189 complementary medicine professionals, paramedical practitioners, dentists, pharmacists and
6
7 190 environmental and occupational health and hygiene professionals. All participants who do not comply
8
9 191 with these criteria will be excluded.

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11 19212
13 193 *Measurements*14
15 194 The primary outcome of this study is the variation in COVID-19 anxiety in different regions, over three
16
17 195 time periods, measured using a modified version of the Swine Flu Anxiety Items [SFI])³⁵ a 10-item
18
19 196 survey developed to measure anxiety disorders and somatization (Cronbach's alpha = 0.85).20
21 197 The secondary outcomes will include:

- 22
-
- 23 198 • the Perceived Vulnerability to Disease (PVD) questionnaire score,
- ³⁶
- a 15-item tool used to
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- 24
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- 25 199 measure subjective vulnerability to disease (Cronbach's alpha = 0.82);
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- 26
-
- 27 200 • the Patient Health Questionnaire (PHQ-9) score,
- ³⁷
- a 9-item tool developed for depression
-
- 28
-
- 29 201 evaluation (Cronbach's alpha = 0.89);
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-
- 31 202 • the Impact of Event Scale-6 (IES-6) score,
- ³⁸
- a 6-items tool for evaluation of symptoms of post-
-
- 32
-
- 33 203 traumatic stress reactions (Cronbach's alpha = 0.80);
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- 34
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- 35 204 • the Connor-Davidson Resilience Scale (CD-RISC 10) score,
- ³⁹
- a 10-item tool, as a short version
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- 36
-
- 37 205 of the CD-RISC 25,
- ⁴⁰
- to evaluate individual resilience (Cronbach's alpha = 0.85);
-
- 38
-
- 39 206 • the Work-Sense of Coherence Scale (Work-SoC) score,
- ⁴¹
- a 9-item tool to evaluate the
-
- 40
-
- 41 207 perceived comprehensibility, manageability and meaningfulness of an individual's current work
-
- 42
-
- 43 208 situation (Cronbach's alpha = 0.83);
-
- 44
-
- 45 209 • a globally measured current risk perception for becoming infected while working, as assessed
-
- 46
-
- 47 210 by a self-created item "I am afraid I will become infected with COVID-19 while on the job"
-
- 48
-
- 49 211 (measured on a visual analogue scale from 0-10);
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- 50
-
- 51 212 • a globally measured current perception of the stress at work, as a second self-created item
-
- 52
-
- 53 213 "How stressful is your current work situation for you?" (measured on a visual analogue scale
-
- 54
-
- 55 214 from 0-10);
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- 56
-
- 57 215 • socio-demographic variables, and work-related and COVID-19-related characteristics: country
-
- 58
-
- 59 216 and city of current occupation, age, sex, profession, main working place, years working in the
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-
- 217 healthcare system, belonging to a risk population, sharing a household with other people, being

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2
3 218 in a relationship, having children, being pregnant or living with a pregnant woman, private close
4
5 219 contact with people belonging to the risk population, having had direct contact with COVID-19–
6
7 220 infected patients, being infected with COVID-19, having been positively tested for COVID-19
8
9 221 antibodies.

10 222

11 223 *Sample size calculation*12 224 The required sample size was calculated using an *a-priori* power analysis with G*Power 3.1.⁴²13 225 Assuming a small effect size ($f^2 = .15$) for a repeated measure ANOVA with three time points and14 226 within-between interaction ($\alpha = .05$, $1-\beta = .95$), the minimum required sample size for four language15 227 groups was $n = 160$. To compensate for drop-out over the three measurement times, we will aim for

16 228 400 responders.

17 229

18 230 *Statistical analysis plan*

19 231 To accommodate between- and within-effects in light of possibly unequal numbers of observations,

20 232 hierarchical linear mixed models will be fit to the longitudinal measures of the primary and secondary

21 233 outcome variables.⁴³ Hierarchical linear regression accounts for non-independence of observations22 234 and attrition inherent in longitudinal data.⁴³ The analyses will be conducted using the R-package:23 235 nlme⁴⁴ in R Statistical Language,⁴⁵ using full maximum likelihood estimations. The normal distributions

24 236 of the outcome variables will be examined by residual diagnostics of the fitted multilevel models.

25 237 For each primary and secondary outcome variable, the analysis will proceed according to

26 238 different steps⁴³. First, a null model (intercept only model) will be estimated, which allows an

27 239 estimation of the proportion of variation in the outcome variables; i.e., between and within the persons

28 240 in the sample. The first model (unconditional growth model with random intercept) will examine the

29 241 within-persons trajectories of change across measurement points. The second model (conditional

30 242 growth model with random intercept and cross-level interaction) will examine the effects of country/

31 243 front-line and second-line HCPs across the different times (i.e., the pandemic phase).

32 244 To address the research questions that are focussed on the relationships between the

33 245 different outcome variables and the resilience and work-related sense of coherence, structural

34 246 equation modelling will be performed⁴⁶. These analyses will be carried out using the R-package:35 247 lavaan⁴⁷ in the R Statistical Language,⁴⁵ using full maximum likelihood estimation.

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3 248 Statistical strategies for dealing with threats to internal validity (i.e. attrition bias, sample
4
5 249 selectivity bias, multiple-testing bias) include extensive drop-out analyses³³, reporting of attrition by
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7 250 socioeconomic factors³³, statistical comparison of participants key characteristics with population
8
9 251 characteristics, and applying of linear hierarchical regression analyses, which include all available
10
11 252 data⁴¹ and compensate for multiple testing⁴⁸.

12 253

14 254 ***Qualitative phase: semi-structured interviews***

16 255

18 256 ***Data collection***

20 257 After completion of the online survey, the participants will be invited to participate in the semi-
21
22 258 structured interviews. We will select all of the participants for the qualitative phase according to
23
24 259 availability and region. We will select them from the pool used in the quantitative phase, so as to best
25
26 260 represent their experience and views. As the study is sequential in nature, it is impossible to pre-
27
28 261 emptively select participants for the qualitative phase. Therefore, we will perform stratified purposive
29
30 262 sampling into homogeneous focus groups, stratified by front- or second-liners, profession and country
31
32 263 of origin, to enable comparisons^{49 50}. We aim to perform at least nine semi-structured interview
33
34 264 groups. All interviews will be coded in a phased fashion, with interim analysis to check for saturation
35
36 265 (i.e., when additional data do not lead to any new themes). If saturation is not reached, three more
37
38 266 interviews will be performed. Sixty-minute semi-structured interviews will be conducted after the
39
40 267 quantitative phase is finished, in different locations in Europe. The aim is to explore participants' views
41
42 268 on the influence of resilience and a work-related sense of coherence on the development of anxiety,
43
44 269 depression and trauma-stress disorder during the pandemic outbreak. We used the protocol proposed
45
46 270 by Castillo-Montoya⁵¹ to develop a semi-structured interview guide (Supplemental Digital Content 2).
47
48 271 We first ensured that interview questions were aligned with our research questions, we then
49
50 272 constructed an inquiry-based conversation, we asked for external feedback on interview protocols and
51
52 273 we will pilot the interview guide in the near future. The interview data will consist of the audio and
53
54 274 video recordings, which will be further transcribed by two members of the study team.

55 275 Strategies for dealing with threats to validity of the qualitative data used in this study include
56
57 276 method triangulation, member-checking (also known as participant validation)⁵², peer support and an

1
2
3 277 audit trail. The use of triangulation of different data sources will enhance objectivity and strengthen
4
5 278 intersubjective agreement⁵³. A thorough methodologic description will also help credibility.
6

7 279

8
9 280 *Analysis plan*

10 281 All of the data will be processed with the software MaxQDA2020 (Verbi, Berlin, Germany). Data
11
12 282 originating from the semi-structured interviews will be processed according to the Miles and
13
14 283 Huberman⁵⁴ framework for data analysis. This initially includes data reduction – including segmenting,
15
16 284 editing and summarising the data – followed by data display, and finally conclusions verification. Two
17
18 285 investigators will code the first group interviews independently and will agree on the coding scheme
19
20 286 for the remaining interviews. Respondent validation and paired coding will be performed as a way to
21
22 287 increase quality. Memoing will be performed parallel to coding.
23

24 288

25
26 289 *Trial status*

27
28 290 The trial started to recruit participants for the first round of the survey (quantitative data) on 2 April,
29
30 291 2020, for a period of 2 weeks. The next rounds are planned for July and October 2020. After the
31
32 292 quantitative data collection ends, we will move on to the qualitative phase.
33

34 293

35
36 294 *Ethics and Dissemination*

37 295 The Bern Cantonal Ethics Committee waived the need for ethical approval on 1 April, 2020, according
38
39 296 to the Swiss Act for Human Research (BASEC Nr. 2020-00355, Prof. Dr. med Christian Seiler,
40
41 297 Murtenstrasse 31, 3010 Bern, Switzerland, Tel: +41-31-6337070, info.kek.kapa@gef.be.ch). All
42
43 298 procedures for this investigation will follow the Helsinki Declaration.⁵⁵
44

45 299 All of the participants will be sent a link to the survey, with a detailed cover letter that explains
46
47 300 the entire project, the purpose of the project, the context of the research, and the contacts of the lead
48
49 301 investigator (available at https://psyunibe.qualtrics.com/jfe/form/SV_3WYgbkLWqiDPDG5). Electronic
50
51 302 informed consent to participate will be obtained from all of the participants at the beginning of the
52
53 303 survey. Should any participants decide not to participate in the study, their decision will not affect
54
55 304 them in any way. No incentives will be offered or given. Participants will be asked for their e-mail, to
56
57 305 enable contact with them during the follow-up and qualitative phases of the study, and for pairing
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1
2
3 306 purposes. During the interviews, participants' faces will not be included in the video recordings, and
4
5 307 their performances will not be shared with any external subjects.

6
7 308 All of the researchers involved will comply with the Data Protection Act and the Swiss Law for
8
9 309 Human Research. There are no ethical, legal or security issues regarding the data collection,
10
11 310 processing, storage and dissemination for this project. We will neither obtain nor generate sensitive
12
13 311 data, and we do not sign any confidentiality agreement. All data will be stored for up to 10 years after
14
15 312 the project, according to the Swiss Law for Human Research.

16
17 313 This study has been registered at the UK based International Standard Randomised
18
19 314 Controlled Trial Number (ISRCTN) under the registration number: ISRCTN13694948. All relevant
20
21 315 data generated or used by the research project (i.e., raw data, all processed data that directly
22
23 316 underlies the reported results, and all ancillary information necessary to understand, evaluate,
24
25 317 interpret and re-use the results of the study) will be stored on the official server of the Institute of
26
27 318 Psychology, Department of Health Psychology and Behavioural Medicine at the University of Bern. All
28
29 319 of the data are, and will be, password protected and only accessible by SA and HE. The datasets will
30
31 320 be flagged for long-term storage. Datasets flagged for long-term storage are subjected to specific
32
33 321 measures to preserve data integrity and data safety, such as additional back-ups, regular re-writes to
34
35 322 new storage media, and redundant storage in third-party repositories.

36
37 323 The datasets generated and analysed during the current study will be available from the
38
39 324 primary investigator upon reasonable request from university-based research groups with suitable
40
41 325 and answerable research questions. The primary investigator will be responsible for ensuring that
42
43 326 electronic file permissions are correctly assigned and for advising on other aspects of data storage
44
45 327 and security. Both qualitative and quantitative data are expected to be available from March 2021. We
46
47 328 expect no limitations with respect to publishing the data.

48
49 329 The study results will be published in a peer-reviewed international medical journal after the
50
51 330 first trimester of 2021. A full timeline of the project is shown in Figure 1.

52
53 331

54 332 **Public involvement statement**

55 333 This research will be carried out without patient involvement, as patients are not the study subjects.
56
57 334 We have involved the Swiss Association of Assistants and Registrars (VSAO), the Swiss Society of
58
59 335 Anaesthesiology and Reanimation (SGAR) and the European Airway Management Society (EAMS) to
60

1
2
3 336 comment on the study design, and have consulted HCPs on relevant outcomes. After the data
4
5 337 analysis, we will invite them to interpret the results again. We have not had time to invite persons
6
7 338 outside the study group to contribute to the writing or editing of this document, because of the velocity
8
9 339 of the progression of the COVID-19 pandemic.

10 340

11 341 ***Importance of the study***

12 342 Despite the large body of literature that is focussed on the prevalence of mental health symptoms
13
14 343 after catastrophes or natural disasters, the investigation of the resilience of HCPs is scarce,
15
16 344 particularly in the face of a surge capacity. In disaster situations, the prevalence of resilience appears
17
18 345 to depend on adequate preparedness, good social support and proactive coping styles⁹. However,
19
20 346 most disaster sites do not impose social distancing and self-isolation procedures, which might further
21
22 347 compromise the HCP ability to cope. It has been shown before that professionals involved in disaster
23
24 348 relief work can develop post-traumatic growth^{14 15}. Establishing a clear relationship between resilience
25
26 349 and a work-related sense of coherence with the development of mental symptoms during exceptional
27
28 350 situations like the current COVID-19 pandemic might help to identify HCPs who are both particularly
29
30 351 protected and at risk, which will allow the adequate distribution of psychological interventions.
31
32 352 Organisations can also potentiate resilience in their employees by ensuring that they are adequately
33
34 353 trained. This is would be an affordable measure that can save money and resources by keeping the
35
36 354 staff at work and avoiding sick leave.

37 355

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2
3 490 **Authors' contributions:** This study was conceptualised by RG and AF, but all authors contributed
4
5 491 equally to the final methodology. JBE, RG and AF recruited the participants. SA and HE hosted the
6
7 492 survey, performed data collection and analysis. All authors significantly contributed to the writing of
8
9 493 the manuscript. The manuscript was reviewed and edited prior to submission, and all authors agreed
10
11 494 on the final version.

12 495

13 496

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17
18 498 Anaesthesiology and Pain Medicine, Inselspital, Bern University Hospital.

19 499

20 500

24 501 **Competing interest statement:** The authors have no competing interests to declare

25 502

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30 504 **Figure Legend:**

31 505 Figure 1: Project timeline

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37 508 **Additional Files**

39 509 **Supplemental Digital Content 1** – Online Questionnaire

41 510 **Supplemental Digital Content 2** – DARVID guidance document for the interviews

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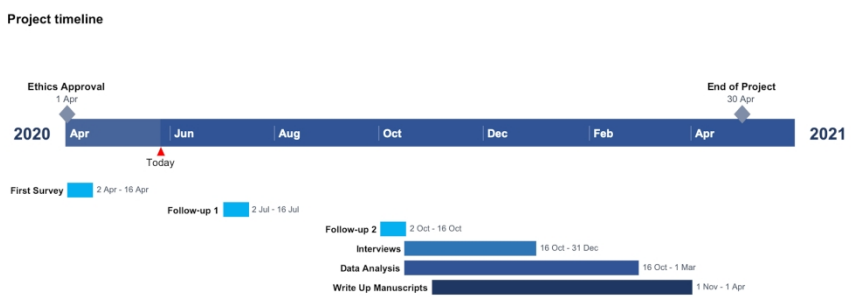


Figure 1: Project timeline
297x209mm (300 x 300 DPI)

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 discussing 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)

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5 Q32 In which city do you currently work?
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8 _____
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14 Q2 Age in years:
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17 _____
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19

20
21 Q3 Your gender?
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- 23
24 Male (1)
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26 Female (2)
27
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29 Other (3)
30
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32 **End of Block: Block 2**
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34 **Start of Block: Block 12**
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37 Q27

38 We need an informed consent from you. Otherwise you cannot participate.
39
40

41
42 Your decision to participate in this study is complete voluntary. If you decide to not participate, it
43 will not affect the care, services, or benefits to which you are entitled.
44
45

46
47
48 If you decide to participate in this study, please go back and indicate "yes".
49
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51
52 **End of Block: Block 12**
53

54 **Start of Block: Block 3**
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2
3 Q11 What is your profession?
4

5 Nurse (1)
6

7 Physician (2)
8

9 Midwife (3)
10

11 Pre-hospital Technician (4)
12

13 Other (what?) (5) _____
14
15

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19
20
21 Q33 Your main working place is:
22

23 ICU (1)
24

25 Anesthesia/Surgery (2)
26

27 Emergency room (3)
28

29 Ward (4)
30

31 Other (where?) (5) _____
32
33

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38
39 Q12 Have you had direct contact (i.e. diagnosed, treated or provided care) with COVID-19
40 infected patients?
41

42 Yes (1)
43

44 No (2)
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51 Q10 How many years are you working in the healthcare system, since graduation?
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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)

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2
3 Q15 Are you pregnant or are you living together with a pregnant woman?
4

5 Yes (1)
6

7 No (2)
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11
12
13 Q14 Do you have close contact in private to people of the risk population mentioned above?
14

15 Yes (1)
16

17 No (2)
18
19

20
21 **End of Block: Block 4**
22

23 -----
24 **Start of Block: Block 14**
25

26 Q33 Are you infected with COVID-19?
27

28 Yes (1)
29

30 No (2)
31

32 Don't know (4)
33
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39 Q34 Have you been positively tested for COVID-19 antibodies?
40

41 Yes (1)
42

43 No (2)
44
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46 **End of Block: Block 14**
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49 **Start of Block: Block 5**
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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)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
To what extent do you believe that COVID-19 could become a "pandemic" in you current resident country? (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How likely is it that you could become infected with COVID-19? (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How likely is it that someone you know could become infected with COVID-19? (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How quickly do you believe contamination from COVID-19 is spreading in your current resident country? (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How much exposure have you had	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

For peer review only

1
2
3 to information
4 about
5 COVID-19?
6 (6)
7

8 If you did
9 become
10 infected with
11 COVID-19, to
12 what extent
13 are you
14 concerned
15 that you will
16 be severely ill?
17 (7)
18

19 To what
20 extend has
21 the threat of
22 COVID-19
23 influenced
24 your
25 decisions to
26 be around
27 people? (8)
28

29 To what
30 extend has
31 the threat of
32 COVID-19
33 influenced
34 your travel
35 plans? (9)
36

37 To what
38 extend has
39 the threat of
40 COVID-19
41 influenced
42 your use of
43 safety
44 behaviors (
45 e.g. hand
46 sanitizer)?
47 (10)
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For peer review only

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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53 End of Block: Block 5

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55 Start of Block: Block 6
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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)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling down, depressed, or hopeless (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trouble falling or staying asleep, or sleeping too much (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling tired or having little energy (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Poor appetite or overeating (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling bad about yourself - or that you are a failure or have let yourself or your family down (6)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trouble concentrating on things, such as reading the newspaper or watching television (7)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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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)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I felt watchful or on-guard. (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other things kept making me think about it. (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I was aware that I still had a lot of feelings about it, but I didn't deal with them. (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I tried not to think about it. (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I had trouble concentrating. (6)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	unmanageable
meaningless	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	meaningful
structured	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	unstructured
easy to influence	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	impossible to influence
insignificant	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	significant
clear	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	unclear
controllable	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	uncontrollable
unrewarding	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	rewarding
predictable	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	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)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I can deal with whatever comes my way. (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I try to see the humorous side of things when I am faced with problems. (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Having to cope with stress can make me stronger. (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I tend to bounce back after illness, injury, or other hardships. (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I believe I can achieve my goals, even if there are obstacles. (6)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Under pressure, I stay focused and think clearly. (7)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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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

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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)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I am unlikely to catch a cold, flu or other illness, even if it's "going around". (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
If an illness is "going around", i will get it. (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My immune system protects me from most illnesses that other people get. (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I am more likely than the people around me to catch an infectious disease. (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My past experiences make me believe I am not likely to get sick even when	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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3 my friends
4 are sick. (6)
5

6 I have a
7 history of
8 susceptibility
9 to infectious
10 disease. (7)
11

12 I prefer to
13 wash my
14 hands pretty
15 soon after
16 shaking
17 someone's
18 hand. (8)
19

20 I avoid using
21 public
22 telephones
23 because of
24 the risk that i
25 may catch
26 something
27 from the
28 previous
29 user. (9)
30

31 I do not like
32 to write with
33 a pencil
34 someone
35 else has
36 obviously
37 chewed on.
38 (10)
39

40 I dislike
41 wearing
42 used clothes
43 because you
44 do not know
45 what the last
46 person who
47 wore it was
48 like. (11)
49

50 I am
51 comfortable
52 sharing a
53 water bottle
54 with a friend.
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<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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(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

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2
3 Last page:
4

5 You have now completed the full questionnaire – Thank you!
6

7
8 Your contribution in this study is of utmost importance to gain insight on healthcare
9 providers' resilience in the present time.
10

11 We will ask you to fill in another shorter questionnaire in summer and in autumn.
12

13 Kind regards,
14

15
16 Prof. Dr. Robert Greif, MME, FERC
17 robert.greif@insel.ch

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19 Dr. phil. Sandra Abegglen
20 sandra.abegglen@psy.unibe.ch
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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.

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-threatening 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?)

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?

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 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

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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)

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- 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**

10 **Methods: Monitoring**

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- 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**

32 **Ethics and dissemination**

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- 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**

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2	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
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6	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
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9	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
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16		31b	Authorship eligibility guidelines and any intended use of professional writers → page 19
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20		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code → page 11-12
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23	Appendices		
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25	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates → page 11-12 & SDC1, page 1
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29	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
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*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.