PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	The COVID-19 Emergency Response Assessment Study; a prospective longitudinal survey of frontline doctors in the UK and Ireland: Study Protocol
AUTHORS	Roberts, Tom; Daniels, Jo; Hulme, William; Horner, Daniel; Lyttle, Mark; Samuel, Katie; Graham, Blair; Hirst, Robert; Reynard, Charles; Barrett, Michael; Carlton, Edward

VERSION 1 – REVIEW

REVIEWER	Matthias Weigl Institute and Outpatient Clinic for Occupational, Social, and Environmental Medicine, Medical Faculty, Ludwig-Maximilians-University Munich, Germany.
REVIEW RETURNED	23-May-2020

GENERAL COMMENTS	Thank you very much for the opportunity to review the study protocol draft "The COVID-19 Emergency Response Assessment Study; a prospective longitudinal survey of frontline Doctors in the UK and Ireland: Study Protocol" (submitted for review, BMJ Open, bmjopen-2020-039851) This protocol outlines a longitudinal study on well-being outcomes during the current COVID-19 pandemic among physicians in E&As, ICUs, and anesthesia units in UK and Ireland. The study consists of three waves of questionnaires, distributed during across different phases of the pandemic. The authors propose that this investigation facilitates our understanding of the trajectories of physical and psychological well-being of doctors during the COVID-19 pandemic, in the short and long term. Given the timeliness of the topic, urgency to collect data during the acceleration and peak waves as well as the dates provided in the manuscript, I assume that the data collection (of the first wave at least) is already been under way. Therefore, I would like to provide a couple of comments (on mostly minor issues) that may help the authors to further strengthen the protocol and clarity of its presentation. Abstract, page 2, please include a short paragraph at the end on the expected input and contribution of your study. As well as one sentence on potential limitations of your approach. Introduction, pages 6 and 7, please provide an explanation why you exclusively focus on doctors in the respective domains, also given the preliminary insights into well-being outcomes observed in healthcare workers during COVID-19 (Lai, Ma, Wang et al., JAMA; who you also cited in your protocol). This paper suggests that the

	harmful effects are (at least as) critical for nurses and other healthcare workers as for physicians. Study design, page 8, please provide a justification for the proposed time lags between each survey; is this proposed by the CDC as well? How will you treat potential differences in the pandemic trajectories between UK and Ireland? (This last point is vaguely discussed in the part on the statistics, page 16, lines 26-36). Measures, pages 8 and 9, the sentences on page 9, lines 16-25: this part on the different methods to treat GHQ-12 reports and data is not clear. Measures, page 9, last para, please provide more and comprehensive information on the personal and professional characteristics being collected. It is currently difficult to extract the relevant information from the survey in the online supplementary. In the supplementary questionnaire also seem to appear more characteristics than are listed in the last sentence (page 9, line 51). Time lags for wave 2 and wave 3, page 14, lines 10-47, also see above. Please provide a justification why you deem that a 7- and 30-day time lags are appropriate. Coding of region and hospital, page 18, lines 28-37, how do you collect information concerning region and/or hospital? This hasn't been described previously. Limitations, I assume that one further limitation pertains to the question how the observed trajectories of well-being can be actually attributed to pandemic related factors, i.e., to discern the effects of conditions associated with COVID-19 compared to more routine, general work life and well-being conditions in emergency and intensive care medicine. There is already a well-established study base on association between work conditions in E&A care and provider well-being outcomes (cf., Schneider & Weigl, 2018). ED and ICU work is demanding, irrespective of pandemics. Inferences concerning the genuine or additional risks caused by COVID-19 need to be considered carefully, i.e., lack of comparative data for "non-COVID-19" phases or conditions. I would suggest to expand the discussion of limitation concerning internal and external validity of the expected study results. I wish the authors best of success for this important study. References cited in this review: Schneider, A., & Weigl, M. (2018). Associations between psychosocial work factors and provider mental well-being in emergency departments: A systematic review. PloS one, 13(6). (doi: 10.1371/journal.pone.0197375)

REVIEWER	Alessandro Tafuri University of Verona, Italy
REVIEW RETURNED	29-May-2020

GENERAL COMMENTS	This is an interesting study protocol that aims to investigate the psychological impact of COVID outbreak in medical staff involved in the frontline critical Units. Here my concerns. This is an important topic that is been reported to not impact only doctors' health care, but also nurses as well as the entire medical

	staff. The authors should better specify why they focused only on doctors. As the authors stated in the discussion, the correct identification of the outbreak Phases related to the Peak Phase may represent a limitation. Probably it was due to the original version for the ethical committee approval was made a few months ago. Could it be currently possible to better define the phases' time due to the current outbreak state? Could the authors better specify the sample size needed (number of participants) for the study, and (in a generic way) the type of statistical tests for study the data relative to this presumed sample size? The authors should specify that all communications (consent and test) have to be sent using Institutional mail addresses.

REVIEWER	Bhakti hansoti Johns Hopkins University, USA
REVIEW RETURNED	14-Jun-2020

GENERAL COMMENTS	This is a great multidisciplinary paper that includes a number of institutions across numerous countries. This is a longitudinal questionnaire based survey, administered to all doctors, that will occur at 3-time points. The outcome measures are two validated surveys GHQ-12 and IES-R. The survey will be electronically administered via REDCap. Unfortunately I am unclear why such a simple survey strategy warrants publication, this is not a clinical trial where publication

VERSION 1 – AUTHOR RESPONSE

Reviewer 1.
Dear Matthias Weigl

In response to your comments, please see below.

Abstract, page 2, please include a short paragraph at the end on the expected input and contribution of your study. As well as one sentence on potential limitations of your approach.

- I have added the below paragraph as requested.
- As a note, I have assumed input = output?

- Page 3 lines 3-7:
- “This study is limited by the fact it focuses on Doctors only and is survey based without further qualitative interviews of participants. It is expected this study will provide clear evidence of the psychological impact of COVID-19 on Doctors and will allow present and future planning to mitigate against any psychological impact.”

Introduction, pages 6 and 7, please provide an explanation why you exclusively focus on doctors in the respective domains, also given the preliminary insights into well-being outcomes observed in healthcare workers during COVID-19 (Lai, Ma, Wang et al., JAMA; who you also cited in your protocol). This paper suggests that the harmful effects are (at least as) critical for nurses and other healthcare workers as for physicians.

- Thank you for this comment. We recognise this is a limitation. It is something that was considered extensively by the study team. We had discussions both with the Royal College of Nursing (RCN)

and College of Paramedics about a larger study.
- The main limiting factor was the rapid development of the study protocol during the pandemic acceleration phase. To enable robust data collection and survey distribution we utilised existing doctor-based research networks. Involving these other important professional groups threatened the validity of the study into Doctors and risked unmitigated distribution of the survey and consequent unknown response rates.
- We supported both the RCN and Paramedic Colleges with set-up of their own studies via advice, open access to the study protocol and liaison with the licence owner to the GHQ-12. We look forward to the results of these separate studies.

I have inserted this paragraph into the protocol for clarity.
- Page 4 lines 19-27
"This study will focus on Doctors and not the wider healthcare workforce. It is well documented that other professions are potentially impacted more by infectious disease outbreaks and by COVID-19. (6) Discussions were held between the study team and representatives from the Royal College of Nursing UK and College of Paramedics UK about a combined study. It was agreed that due to the limited timescale to collect data during the acceleration phase and complexities around different working practices that delaying data collection to involve a wider cohort would threaten the validity of the study. This protocol was shared with the Colleges to support their independent studies, as well as ongoing information sharing to understand the potential psychological impacts of the pandemic upon these groups."

Study design, page 8, please provide a justification for the proposed time lags between each survey; is this proposed by the CDC as well?

-Please see clarifications added to the text:

- Page 13 lines 4-6
- "The 7-day time delay is due to the requirement of the IES-R scale to reflect on feelings over the last 7-days, thus a delay will ensure answers more accurately represent true outcomes from the pandemic peak"
- Page 13 lines 23-27
- The deceleration phase is defined by the CDC as "consistently decreasing rate of cases". [21] To ensure the deceleration survey is released during this phase, it will be released 30 days after the administration of the 'Peak' Survey. This is to ensure UK and Republic of Ireland cases are consistently decreasing and that there is no evidence of a second peak.

How will you treat potential differences in the pandemic trajectories between UK and Ireland? (This last point is vaguely discussed in the part on the statistics, page 16, lines 26-36).

A clarification from the study Statistician Dr William Hulme :

From a statistical perspective region-level random-effects on the intercept and time will be included in both time- and phase-indexed models enabling regional differences in the modelled effect of phase/time on GHQ and IES-R scores to be (partially) accounted for.

This permits more focus on personal factors (that may be indirectly influenced by the local extent of the pandemic at the time of responses) such as the number of witnessed deaths and frequency of contact with COVID positive patients.

Page 7, line 7-9. This has been updated in the text to:
"Region-level random-effects on the intercept and time will be included in both time- and phase-indexed models, enabling regional differences in the modelled effect of phase/time on GHQ and IES-R scores to be (partially) accounted for."

Measures, pages 8 and 9, the sentences on page 9, lines 16-25: this part on the different methods to treat GHQ-12 reports and data is not clear.

- Please see clarification in the text: Page 7 lines 18-28

- The GHQ-12 can be scored using several methods and we will report 2 of these in our results. The first, the 0-0-1-1 scoring method, is the most commonly utilised, and has the highest sensitivity and specificity overall. (23) The strength of this method is that it can identify case level distress, identified if respondents pass the threshold score of >3. (24) The second uses a 0-1-2-3 scoring method to detect within-person changes. The strength of this is that it is deemed more sensitive to changes across time points, however unlike the first method, there is no established cut-off and this technique reflects degree of distress rather than threshold caseness. Therefore, by presenting the 2 different scoring methods the results can more sensitively detect the prevalence of distress (0-0-1-1 scoring method) and the change over the 3 phases of the pandemic (0-1-2-3 scoring method).

Measures, page 9, last para, please provide more and comprehensive information on the personal and professional characteristics being collected. It is currently difficult to extract the relevant information from the survey in the online supplementary. In the supplementary questionnaire also seem to appear more characteristics than are listed in the last sentence (page 9, line 51).

- To make this clearer I have built a table outlining characteristics – now table 1 in the uploaded manuscript (page 8 lines 10 – page 9)

Time lags for wave 2 and wave 3, page 14, lines 10-47, also see above. Please provide a justification why you deem that a 7- and 30-day time lags are appropriate.

Please see clarifications added to the text:
- Page 13 lines 4-6
- “The 7-day time delay is due to the requirement of the IES-R scale to reflect on feelings over the last 7-days, thus a delay will ensure answers more accurately represent true outcomes from the pandemic peak
- Page 13 lines 23-27
- The deceleration phase is defined by the CDC as “consistently decreasing rate of cases”. [21] To ensure the deceleration survey is released during this phase, it will be released 30 days after the administration of the ‘Peak’ Survey. This is to ensure UK and Republic of Ireland cases are consistently decreasing and that there is no evidence of a second peak.

Coding of region and hospital, page 18, lines 28-37, how do you collect information concerning region and/or hospital? This hasn’t been described previously.

-Added to page 9 line 11 to page 10 line 2 for clarity:

- “Participants will be asked to declare the hospital they work in. Hospitals will be grouped into regions as defined by UK Government Coronavirus death reporting. [26]”

Limitations, I assume that one further limitation pertains to the question how the observed trajectories of well-being can be actually attributed to pandemic related factors, i.e., to discern the effects of conditions associated with COVID-19 compared to more routine, general work life and well-being conditions in emergency and intensive care medicine. There is already a well-established study base on association between work conditions in E&A care and provider well-being outcomes (cf., Schneider & Weigl, 2018). ED and ICU work is demanding, irrespective of pandemics. Inferences concerning the genuine or additional risks caused by COVID-19 need to be considered carefully, i.e., lack of comparative data for “non-COVID-19” phases or conditions. I would suggest to expand the discussion of limitation concerning internal and external validity of the expected study results.

- Thank you for this very important point and it is something that we have recognised as a study team.
- Any impacts we identify and their associations with personal or professional factors will be discussed in the context of the broader literature and previous studies outlining pre-COVID-19 rates of distress and/or trauma. We are cognisant of the fact that our data windows do not include a pre-COVID-19 ‘baseline’ and any interpretations will be made in the context of these limitations.
- I have added the following to the discussion for clarity, page 21 lines 16-20:

- “A further limitation to this work is the lack of baseline level of distress or trauma in this cohort prior to the COVID-19 pandemic. Work within the ED, ICU and anaesthetics is already known to be challenging and impact of Doctors psychological health. [8,41,42] Results of this study will be presented in the context of the existing literature predating the COVID-19 pandemic. “

I wish the authors best of success for this important study.

References cited in this review:
Schneider, A., & Weigl, M. (2018). Associations between psychosocial work factors and provider mental well-being in emergency departments: A systematic review. PloS one, 13(6). (doi: 10.1371/journal.pone.0197375)

Reviewer: 2.
Dear Alessandro Tafuri

In response to your comments, please see below.

This is an important topic that is been reported to not impact only doctors' health care, but also nurses as well as the entire medical staff. The authors should better specify why they focused only on doctors.

Thank you for this comment. We recognise this is a limitation. It is something that was considered extensively by the study team. We had discussions both with the Royal College of Nursing (RCN) and College of Paramedics about a larger study.
- The main limiting factor was the rapid development of the study protocol during the pandemic acceleration phase. To enable robust data collection and survey distribution we utilised existing doctor-based research networks. Involving these other important professional groups threatened the validity of the study into Doctors and risked unmitigated distribution of the survey and consequent unknown response rates.
- We supported both the RCN and Paramedic Colleges with set-up of their own studies via advice, open access to the study protocol and liaison with the licence owner to the GHQ-12. We look forward to the results of these separate studies.

I have inserted this paragraph into the protocol for clarity.
- Page 4 lines 19-27
This study will focus on Doctors and not the wider healthcare workforce. It is well documented that other professions are potentially impacted more by infectious disease outbreaks and by COVID-19. (6) Discussions were held between the study team and representatives from the Royal College of Nursing UK and College of Paramedics UK about a combined study. It was agreed that due to the limited timescale to collect data during the acceleration phase and complexities around different working practices that delaying data collection to involve a wider cohort would threaten the viability of the study. This protocol was shared with the Colleges to support their independent studies, as well as ongoing information sharing to support study implementation.

As the authors stated in the discussion, the correct identification of the outbreak Phases related to the Peak Phase may represent a limitation. Probably it was due to the original version for the ethical committee approval was made a few months ago. Could it be currently possible to better define the phases' time due to the current outbreak state?

- The protocol represents our prospective planning for how we would identify the peak prospectively. Whilst we will discuss the accuracy of the peak estimate in the final manuscript, we feel it is important to highlight the process for peak identification in the protocol.

Could the authors better specify the sample size needed (number of participants) for the study, and (in a generic way) the type of statistical tests for study the data relative to this presumed sample size?

A clarification from the study Statistician Dr William Hulme :

- An important component of this study was to describe the experiences of respondents in non-inferential terms, without formal significance tests and without specific hypotheses being declared and tested. As such, the study does not rely on significant tests that require formal sample size calculations to be made. However, we of course acknowledge that with an insufficient sample size there is very little that can be understood about the target population, though given we anticipated (and have since achieved) well over 1000 responses (and so for example estimates of mean GHQ would be comfortably within 1 unit of precision for any reasonable prior on the variance of GHQ), a formal sample size calculation on any population summary measure would not have precipitated a material change the design of the study, or the approach to data collection.

The authors should specify that all communications (consent and test) have to be sent using Institutional mail addresses.

-The following 2 changes have been made to highlight that study communications will be from institutional email addresses
- Page 10 line 9"…will be invited to register as participating sites via institutional email"
- Page 12 lines 6-12 "All participants who completed the Phase 1 survey will be invited via the REDCap invite function to complete Phase 2 and 3 surveys. This uses a secure institutional email to deliver email invitations."

Reviewer 3.
Dear Bhakti Hansoti,

In response to your comments, please see below.

Unfortunately I am unclear why such a simple survey strategy warrants publication, this is not a clinical trial where publication

- This is not a clinical trial, however it was felt best practice to publish the protocol to highlight our primary aims and objectives so that we can be as scientifically robust as possible, this is in line with transparent and open science. This is of great importance at a time where we have seen prominent examples of where poor research governance has resulted in withdrawal of manuscripts from prominent journals.
- As a study team we feel the points laid out by the BMJ and their rationale behind publishing study protocols, (https://authors.bmj.com/before-you-submit/how-to-write-a-study-protocol/) is as applicable to longitudinal survey work as other types of research.

VERSION 2 – REVIEW

REVIEWER	Matthias Weigl Institute and Outpatient Clinic for Occupational, Social, and Environmental Medicine, University Hospital of Ludwig-Maximilians-University Munich
REVIEW RETURNED	04-Jul-2020

GENERAL COMMENTS	Thank you very much for this review invitation. The authors addressed all my and reviewer 1's and #3's previous comments and carefully revised the draft. The revised manuscript gained clarity and comprehensibility. I recommend publication. I just spotted a few minor issues: manuscript page 4, line 38, correct to doctors (small cap letter) page 14, line 18, correct to Phase 2 survey same for page 14, line 32 (this is insonsistent in the MS, see also page 19, line 17)

	pages 23/24, given that you investigate incidences of trauma and distress, potential selection bias may occur such that doctors who are severely affected may not be included at phase 2 or 3 (i.e., due to being on certified sick leave; or undergoing hospital treatment). I would suggest to consider this as a potential limitation. Thank you very much and I wish the authors best of success for this important prospective survey.

REVIEWER	Alessandro Tafuri University of Verona, Verona, Italy
REVIEW RETURNED	30-Jun-2020

GENERAL COMMENTS	The authors answered and modified properly the manuscript according to reviewers' comments. I think this is a very interesting project. Congratulations.

VERSION 2 – AUTHOR RESPONSE

Reviewer: 1
Dear Matthias Weigl,

Thank you again for taking the time to review the protocol and for your helpful comments.

manuscript page 4, line 38, correct to doctors (small cap letter)
• Thank you, this has been updated.

page 14, line 18, correct to Phase 2 survey.
same for page 14, line 32 (this is insonsistent in the MS, see also page 19, line 17)

• I have reviewed the entire manuscript section and ensured ‘phase’ relates to the correct phase of the study. I have also ensured the wording is consistent.

pages 23/24, given that you investigate incidences of trauma and distress, potential selection bias may occur such that doctors who are severely affected may not be included at phase 2 or 3 (i.e., due to being on certified sick leave; or undergoing hospital treatment). I would suggest to consider this as a potential limitation.

• Thank you for this comment, as a study team this has been discussed and is definitely a limitation.
• In the final analysis we will look at the GHQ-12 scores for those who dropped out and present this as part of the final analysis.
• I have added the following to the limitations section:
• “There is a risk of selection bias through participant drop-out from survey 1 to surveys 2 and 3. To mitigate against this the GHQ-12 and IES-R results for those who drop-out will be presented in the final analysis.”