Cover Page for ClinicalTrials.gov

Official Title of the Study:

The COVID-19 and Healthcare Workers: An Active Intervention

NCT Number:

NCT04497415

Principal Investigator:

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646-774-8041

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Statistical Analysis Plan

Data will be analyzed using SPSS Statistics 26.0 for Mac. We will use Pearson's chi-squared ($\chi 2$) and one-way analysis of variance (ANOVA) to compare demographic variables and baseline psychopathological characteristics of the three groups. To represent within-participant dependencies in the models, we will specify an unstructured correlation matrix. We will first apply a full factorial model across the four time points (baseline, post-intervention, 14- and 30-day follow-ups) for treatment-seeking intentions and three time points (baseline, 14- and 30-day follow-ups) for clinical symptoms. Group × time interaction terms will test the intervention effect hypothesis of greater treatment-seeking in the two video groups. If between-group differences are found, post hoc tests will be used to compare each group pair, including the overall changes from baseline assessment to 30-day follow-up. Effect sizes will be reported using Cohen's d when appropriate. All statistical tests will be two-sided, using $\alpha < 0.05$.

Protocol Title:
The COVID-19 and healthcare workers: an active intervention

Version Date:
10/20/2020

Protocol Number:
8032

First Approval:
07/13/2020

Clinic:
Anxiety Disorders Clinic

Expiration Date:
No Expiration

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Cover Sheet

Choose ONE option from the following that is applicable to your study
If you are creating a new protocol, select "I am submitting a new protocol." As 5 Year Renewals are no longer required, this option remains for historical purposes.
I am proposing an amendment only to an existing protocol

Division & Personnel

Division

What Area Group does the PI belong to?
What Division/Department does the PI belong to?
Anxiety Disorders Clinic
Within the division/department, what Center or group are you affiliated with, if any?
PTSD team

Unaffiliated Personnel

List investigators, if any, who will be participating in this protocol but are not affiliated with New York State Psychiatric Institute or Columbia University. Provide: Full Name, Degrees and Affiliation.
n/a

Amendment

Describe the change(s) being made

Currently, we assess participants at pre-intervention, post-intervention, 14-day follow-up and 30-day follow-up. **For each step of the study the compensation fee is $1.10.**
We would like to add a 90-day follow-up, and conduct the same assessment as in 30-day follow-up and to add 1 item to inquire if the participant contacted mental health professionals.
In addition, the overall compensation for the study is now $4.40.

Provide the rationale for the change(s)
We would like to understand longer-term effects of the intervention and if an observed change in help-seeking intentions is translate to change in help-seeking behavior.
Comment on the extent to which the proposed change(s) alter or affect risks/benefits to subjects
We assess that there is no affect on risks/benefits to subject.
Comment on if the proposed change(s) require a modification to the Consent Form (CF)
We don't think a change in CF is needed.

Procedures

To create the protocol summary form, first indicate if this research will include any of the following procedures
✓ Internet-based Data Collection or Transmission

Population

Indicate which of the following populations will be included in this research
✓ Adults
✓ Adults over 50

Research Support/Funding

Will an existing internal account be used to support the project?
Yes
Describe internal account

Account RFMH: 2801D
Is the project externally funded or is external funding planned?
No

Study Location

Indicate if the research is/will be conducted at any of the following
✓ NYSPI
This protocol describes research conducted by the PI at other facilities/locations
No

Lay Summary of Proposed Research

Lay Summary of Proposed Research
The COVID-19 outbreak exceeds scope and magnitude of most previous disasters over the last 100 years, and has a significant impact upon mental health. It entails a blend of risk factors for both acute and long-term mental health problems. Data that is started to emerge from the COVID-19 outbreak, suggest that front lines health workers (doctors; nurses) are particularly at risk for depression, anxiety and PTSD. Others may develop moral injury, a profound psychological distress which results in actions, or the lack of them, which violet one's moral or ethical code. Given the magnitude of the COVID-19 outbreak, its risk to physical and mental health, an effective and timely response is essential to address the psychosocial needs associated with the ongoing exposure to disease, death, and distress among health care providers, across low and high risks areas.
Many health care providers reluctant to seek support from friends and family, as well as mental health care due to stigma and fear. Despite enduring symptoms, they may wait months to years before they seek help. Applying strategies to reduce stigma and fear towards mental health care and improve help seeking behavior may ameliorate impaired functioning and reduce risks for long-term psychiatric illness.
Studies have shown that social contact is the most effective type of intervention to reduce stigma-related attitudes and to improve help-seeking behavior. The overarching goal of this study is to examine the efficacy of video intervention in reducing stigma and fear, and improving help seeking behavior among health care providers (N=1,200), with pre-, post- and follow up assessments (day 14, day 30 **and day 90**). Participants will be randomly assigned to either a) a video-based intervention (day 1 and a "booster intervention" of the same content on day 14 of the study) featuring the personal story of a health care provider with COVID-19, his struggles and barriers to care, (b) video-based intervention (day 1 only), and a written description of the same story on day 14 (c) no-intervention control arm (questionnaires only).
We aim to (1) determine whether video-based intervention reduce stigma and fear, and increase help-seeking behavior in relation to COVID-19 among health care providers, and (2) compare high risk areas (e.g., NY) to low risk areas (e.g., Montana) on intervention outcomes, and (3) test whether symptoms of depression, anxiety, PTSD and Moral Injury, that will be measured by Patient Health Questionnaire (PHQ-9), Generalized Anxiety Disorder (GAD-7), the Primary Care PTSD Screen for DSM-5 (PC-PTSD-5), and the Moral Injury Events Scale (MIES) would change overtime.

Background, Significance and Rationale

Background, Significance and Rationale
Coronavirus disease 2019 (COVID-19) has widely and rapidly spread around the world. To effectively respond to the COVID-19 outbreak, various governments have implemented rapid and comprehensive public health emergency interventions that include social restrictions and quarantines, which is the separation and restriction of movement of people who might have been exposed to the virus. While the physical risk (e.g. pneumonia, respiratory breakdown) is getting the most scientific and clinical attention, this outbreak also has significant mental health risks and extreme psychological fear-related responses. Psychological responses to previous large-scale outbreaks, particularly to the Ebola Virus Disease (EVD) epidemic during 2014-2016, provide insight into the potential impact of rapidly spreading diseases on mental health problems (1). During the Ebola outbreak, fear-related behaviors such as stigmatizing infected survivors and ignoring medical procedures impeded public health efforts and negatively affected recovery of survivors (2). Anxiety, posttraumatic stress disorder (PTSD), and depression were found in nearly half of the EVD survivors and their contacts (2).
The COVID-19 outbreak exceeds scope and magnitude of most previous disasters over the last 100 years. It entails a blend of risk factors for both acute and long-term mental health problems. Data that is started to emerge from the COVID-19 outbreak, suggest that front lines health workers (doctors; nurses) are particularly at risk. A recent study (3) in 1257 health care workers from 34 hospitals, conducted between January 29 to February 3, 2020, revealed that more than half (50.4%) of the health workers were screened positive for depression, 44.6% for anxiety, and 34.0% for insomnia. Consistent with previous disaster studies (4) a dose response relationship was found between level of exposure and outcomes. Others may develop moral injury, a profound psychological distress which results in actions, or the lack of them, which violet one's moral or ethical code (5,6). Given the magnitude of the COVID-19 outbreak, its risk to physical and mental health, an effective and timely response is essential to address the psychosocial needs associated with the ongoing exposure to disease, death, and distress among health care providers, across low and high risks areas.
Many health care providers reluctant to seek support from friends and family, as well as mental health care due to stigma and fear (e.g., "it would be too embarrassing", "I would be seen as week")(4). Despite enduring symptoms, they may wait months to years before they seek help (7). Among reasons to avoid seeking mental health care, individuals report mistrust in mental health providers, being seen as weak or stereotyped as "crazy", and a belief that they may be responsible for having mental health problems (8,9). Applying strategies to reduce stigma and fear towards mental health care and improve help seeking behavior may ameliorate impaired functioning and reduce risks for long-term psychiatric illness.
Studies (10) have shown that social contact is the most effective type of intervention to reduce stigma-related attitudes and to improve help-seeking behavior. Social contact involves interpersonal contact with members of the stigmatized group: members of the general public who meet and interact with individuals who suffer from stress, fear, depression or anxiety and seek mental health care, are likely to lessen their stigma. Corrigan (11) identified the most important ingredients of contact-based programs: an empowered presenter with lived experience who attains his/her goals (e.g., "I was able to fight the depression/distress that I had following the COVID-19"). While both direct, in-person social contact and indirect, video-based social contact have effectively improved attitudes toward mental issues and care, the latter can be implemented on a larger scale, use a minimal resource and easily disseminated (12-14).

Specific Aims and Hypotheses

Specific Aims and Hypotheses
The overarching goal of this study is to examine the effect of video intervention in reducing stigma and fear, and improving help seeking behavior among health care providers across the US.
In a sizable randomized controlled trial (N=1,200, general population), with pre-, post- and follow-up assessments (day 14, day 30 **and 90 day**), we aim to (1) determine whether video-based intervention reduce stigma and fear, and increase help-seeking behavior in relation to COVID-19 among health care providers, and (2) compare high risk areas (e.g., NY) to low risk areas (e.g., Montana) on intervention outcomes, and (3) test whether symptoms of depression, anxiety, PTSD and Moral Injury, that will be measured by Patient Health Questionnaire (PHQ-9), Generalized Anxiety Disorder (GAD-7), the Primary Care PTSD Screen for DSM-5 (PC-PTSD-5), and the Moral Injury Events Scale (MIES) would change overtime.
Hypotheses: We hypothesize that (1) the brief video intervention will have greater impact in reducing stigma and fear, and in increasing help-seeking behavior in relate to COVID-19 than the control groups in comparison to pre-intervention and to non-video conditions, (2) High risk areas will have increased baseline rates of anxiety, depression and PTSD, and (3) the brief video is expected to have greater impact in reducing symptoms of depression, GAD and PTSD.

Description of Subject Population

Sample #1

Specify subject population
US adults health care workers
Number of completers required to accomplish study aims
1200
Projected number of subjects who will be enrolled to obtain required number of completers
1200
Age range of subject population
18-80

Gender, Racial and Ethnic Breakdown
It is expected the sample will roughly mirror the US healthcare workers population:
Anticipated gender distribution: 73% female, 27% male
Anticipated racial distribution: 72% white only, 21% African American only, 5% Asian only, 2% other, 5% 2+ races
Anticipated Hispanic Ethnic Distribution: 10% Hispanic, 90 % Non-Hispanic
Description of subject population
Participants recruited using Amazon Mechanical Turk (AMT) will be adults in the U.S.

Recruitment Procedures

Describe settings where recruitment will occur
Participants will be recruited via Amazon Mechanical Turk (AMT: https://www.mturk.com/mturk/). AMT is a website that allows interested people across the US to respond to tasks, including completion of surveys, for a small amounts of compensation. AMT requires users to be over 18 years old. For this study the age range will be defined as 18-80. No demographic restrictions will be placed on participants, other than being health care workers and a resident in the U.S.
How and by whom will subjects be approached and/or recruited?
A posting (the Information Sheet attached to this protocol) will be listed on AMT once the study is approved by IRB. Participants can peruse the tasks available via AMT and read the information posted if they desire. The posting will explain the terms and conditions of the study. If participants agree to the conditions and consent to participate, they will click on a link that will direct them to complete the study procedures via Qualtrics.com (a secured, online data-collection platform that will store the study data in a password protected
account); if they do not consent to the conditions, they will not participate.
How will the study be advertised/publicized?
As stated above, a posting (the Information Sheet attached to this protocol) will be listed on AMT once the study is approved by the IRB. In answering "yes" to the question below about whether we have recruitment material requiring review, we are referring to the Information Sheet.
Do you have ads/recruitment material requiring review at this time?
Yes
Does this study involve a clinical trial?
No

Concurrent Research Studies

Will subjects in this study participate in or be recruited from other studies?
No

Inclusion/Exclusion Criteria

Name the subject group/sub sample
AMT participants
Create or insert table to describe the inclusion criteria and methods to ascertain them

Study Criteria	Methods of Ascertainment
Healthcare workers	AMT setting will be used to limit responders to of healthcare workers only
80>Age>18	AMT requires responders to be at least 18 years old and lower than 80

English speakers	AMT settings will be used to limit responders to English speakers only
US residents	AMT settings will be used to limit responses to users in US only

Create or insert table to describe the exclusion criteria and methods to ascertain them

Study Criteria	Methods of Ascertainment
Age<18	AMT requires responders to be at least 18 years old
Age>80	AMT settings will be used to limit the age to 80 years old
Non healthcare workers	AMT settings will be used to ensure that only healthcare workers will participate
Non English speakers	AMT settings will used to ensure that only English speakers will participate.

Waiver of Consent/Authorization

Indicate if you are requesting any of the following consent waivers
Waiver of consent for use of records that include protected health information (a HIPAA waiver of Authorization)
No
Waiver or alteration of consent
No
Waiver of documentation of consent
Yes
Waiver of parental consent
No

Consent Procedures

Is eligibility screening for this study conducted under a different IRB protocol?
No
Describe procedures used to obtain consent during the screening process
n/a
Describe Study Consent Procedures
As stated earlier, a posting (the Information Sheet attached to this protocol) will be posted on AMT once the study is approved by the IRB. Participants can peruse the tasks available via AMT and read the information posted if they desire. The posting will explain the terms and conditions of the study. If participants agree to the conditions and consent to participate, they will click on a link that will direct them to complete the study

procedures via Qualtrics.com (a secure, online data-collection platform that will store the study data in a password-protected account); if they do not consent to the conditions, they will not participate.
Indicate which of the following are employed as a part of screening or main study consent procedures
✓ Information Sheet

Waiver of Documentation of Consent

Would the consent form signature be the only link between the subject's identity and the research data?
Yes
Is breach of confidentiality the main study risk?
Yes
Describe the study component(s) for which waiver of documentation is requested
The information sheet will act as consent, but no signature will be obtained because the information sheet will be presented onscreen to participants recruited via the internet.

Persons designated to discuss and document consent

Select the names of persons designated to obtain consent/assent
Type in the name(s) not found in the above list
n/a

Study Procedures

Describe the procedures required for this study

Participants will be randomly assigned to either a) a 120-second video-based intervention (day 1 and a "booster intervention" of the same content on day 14 of the study) featuring the personal story of a health care provider with COVID-19, his struggles and barriers to care, (b) video-based intervention (day 1 only), and a written description of the same story on day 14 (c) no-intervention control arm (questionnaires only).

Participants of all study arms will be invited to participate in a follow up survey in days 14, 30 **and 90**. We will invite the participants by using AMT messaging system.

The video content/written vignette: "Martha is a 35-year-old nurse who lives in NYC with her husband (Dave). She works at intensive care unit in a large hospital, and her husband was fired recently from his job as a waiter due to COVID-19. She has never been diagnosed with anxiety, depression or any other mental health issues. Lately, she finds herself experiencing nightmares as well as unexpected fears. She is feeling worried about money, about what might happen if she becomes infected with COVID-19, and about the safety of her parents as well. To Martha it seems that everything has changed since the pandemic began. Recently these worries mean she has had trouble falling asleep, she feels depressed and he feels anxious. Her husband suggested that she could try seeking help. When he first suggested this she dismissed him

saying, “What if people know I went to a psychologist? They might think I’m crazy. Also, what if they suggest I take meds? I don’t want to take any... And if my colleges found out they might think I’m weak...”. Martha was very resistant to even the idea at first. After a while however, when she realized that how she felt was only getting worse, she agreed to seek professional help. She found a therapist that she now meets with once a week, and since this started, she has reported that she is feeling much better."

You can upload charts or diagrams if any

Assessment Instruments

Create a table or give a brief description of the instruments that will be used for assessment
Questions for the pre- and post-intervention (day 1) and follow-ups (day 14, day 30 and **day 90**).
Baseline Questionnaire (will be conducted pre intervention only) will include four questions regarding demographics (age, sex, ethnicity and race). Based on previous studies it is estimated the response time will be around 30 seconds.
Three questionnaires will be conducted at pre- and post-intervention (day 1) and follow-up (day 14, day 30 and **day 90**):
1. Attitude towards COVID-19 – attitude towards COVID-19 questions were adapted from a measure created by Berger et al. about stigma and fear towards people with HIV. The questionnaire will include six questions and based on previous studies it is estimated the response time for 50 seconds.
2. Attitude towards seeking help - Attitude towards help seeking will be based on the ATSPPH-SF (Attitudes Towards Seeking Professional Psychological Help Scale), and will include 5 questions (0-disagree, 3-agree). One table will be created to include all 5 questions in one screen. Based on previous studies it is estimated the response time will be around 40 seconds.
3. COVID-19 related behaviors and experiences was developed by the researchers and will include six questions regarding social media use, news consumption, social contact, previous contact with a known COVID-19 patient and if the participant has been tested for COVID-19. It is estimated the response time will be around 50 seconds.
Three questionnaires will assess clinical symptoms and will be conducted at pre-intervention (day 1) and follow-up (day 14, day 30, and **day 90**):
1. GAD-7 questionnaire will include 7 questions that assess anxiety
2. PHQ-9 questionnaire will include 9 questions to assess depression
3. Primary Care PTSD screen for DSM-5 will include 5 yes/no questions to assess PTSD. Three tables will be created, one for each questionnaire. Based on previous studies it is estimated the response time will be 150 seconds.
One questionnaire will assess Moral Injury (MIES), and includes 9 items (50 seconds).
In sum, the estimate time for day 1 (pre and post intervention) is 7-9 minutes for intervention groups and 5-7 minutes for control. The estimate time for each follow up is 4-7 minutes (days 14, 30 **and 90**).

In day 90, we will add the following question:
Over the last three months (you may choose more than one answer):
1. I started to take medications to improve my mental condition
2. I started psychological treatment

3. I contacted professionals (via email/phone/in person) regarding the possibly of starting a psychological treatment
4. I am planing to contact professionals regarding the possibility of starting a psychological treatment in the future
5. None of the above
6. Prefer not to answer

Please attach copies, unless standard instruments are used

Research Related Delay to Treatment

Will research procedures result in a delay to treatment?
No
Treatment to be provided at the end of the study
None. No treatment is involved in this study, and the study does not prevent any participant from undergoing treatment for any medical problem.

Risks/Discomforts/Inconveniences

Risks that could be encountered during the study period
Breach of confidentiality is the main risk of the study. Another potential risk is that participants may experience mild psychological distress when answering questions about COVID-19, due to its sensitive nature.
Describe procedures for minimizing risks
For both of these risks, participants will be reminded that their responses are completely anonymous and that they are free to select "prefer not to answer" if they do not wish to answer a question or end their study participation at any time. Further ways to address the risk of breach of confidentiality are discussed in the Methods to Protect Confidentiality section.

Methods to Protect Confidentiality

Describe methods to protect confidentiality
AMT protects confidentiality in keeping with the Amazon.com privacy policies. No identifiable information concerning participants' responses is shared with anyone outside the research team.
The investigators of this research will only have access to the de-identified responses and associated demographic data of the respondents. We will not use any identifying information as IP addresses, and therefore will be unable to identify any individual respondent. Hence, we are requesting a waiver of the documentation of consent.

Will the study be conducted under a certificate of confidentiality?

No

Direct Benefits to Subjects

Direct Benefits to Subjects
There is no foreseeable benefit to subjects.

Compensation and/or Reimbursement

Will compensation or reimbursement for expenses be offered to subjects?
Yes
Please describe and indicate total amount and schedule of payment(s).
Include justification for compensation amounts and indicate if there are bonus payments.
Participants will be compensated $4.40 in total for participating in the study ($1.10 for day 1, $1.10 for the follow-up on day 14, $1.10 for the follow-up on day 30, **and $1.10 for the follow-up on day 90)**), a competitive rate on AMT for such a short study. At the conclusion of each part of the study, a "completion code" is displayed to each participant by the Qualtrics software. Participants are instructed to input this code on the AMT web page where they signed up to participate in the study. Once a participant completes the study and inputs the correct code, the researchers will credit $1.10 to his/her AMT user account on each day of participation (for a possible total of $4.40). There are no bonus payments associated with this study.

References

References
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Uploads

Upload copy(ies) of unbolded Information Sheet(s)
Information Sheet. version 3. unbolded. 10.19.2020.pdf
Upload copy(ies) of bolded Information Sheet(s)
Information Sheet. version 3. bolded. 10.19.2020.pdf
Upload copy(ies) of recruitment materials/ads to be reviewed
Study Advertisement. version 3. unbolded. 10.19.2020.pdf
Study Advertisement. version 3. bolded. 10.19.2020.pdf
Upload copy(ies) of the HIPAA form
Upload any additional documents that may be related to this study