Cover Page for ClinicalTrials.gov

Official Title of the Study:

The COVID-19 Pandemic and Veterans: An Active Intervention

NCT Number:

NCT04484207

Principal Investigator:

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Statistical Analysis Plan

Data will be analyzed using SPSS 26.0. We will use Pearson's Chi-square and one-way ANOVA to compare demographic variables, baseline psychopathological characteristics, and baseline ATSPPH-SF scores of the three groups. We will use Independent t-tests to compare baseline psychopathological characteristics (continuous variables), and Chi-square tests to compare the severity of each psychopathology (ordinal variables) of participants who do and do not report Covid-19 exposure. All statistical tests will be 2-sided, using $\alpha<0.05$.

Intervention effects will be tested using the generalized estimating equations (GEE) approach, as recommended for randomized controlled trials. The GEE approach accounts for correlated repeated-measures analysis and accommodates missing data via estimated marginal means relying on the entire sample. Thus, this analytic strategy includes data from all randomized participants who provide at least one data point. To represent within-subject 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 and 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. Time-by-group interaction terms will be used to test the intervention effect hypothesis of greater treatment-seeking in the video group. For significant differences, post hoc tests will be used to compare each group pair. Effect sizes will be reported using Cohen's d when appropriate.

Protocol Title:
The COVID-19 pandemic and veterans: An active intervention

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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.

Department & Unaffiliated Personnel

Department

What Department does the PI belong to?
Anxiety Disorders Clinic
Within the 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

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

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Coronavirus disease 2019 (COVID-19) has widely and rapidly spread around the world, overwhelming intensive care units and health care capacity. 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. Among the general population, there are high-risk groups as elderly people, disabled individuals and people with previous exposure to trauma (e.g., people with military experience). Veterans are among the subgroups who are high risk for PTSD and other mental health problem. The overarching goal of this study is to examine the efficacy of an online, large-scale, brief video-based intervention in reducing fear and stress and improving help seeking behavior in relate to COVID-19.

In a sizable randomized controlled trial (N=2,000), with pre-, post- and follow-up assessments the *aim* is to (1) determine whether video-based intervention reduce self-stigma and social media use and increase help-seeking behavior in relate to COVID-19 among people with military experience, and to (2) test the effect of the intervention in reducing symptoms of depression, anxiety and PTSD, that will be measured by Patient Health Questionnaire (PHQ-9) and Generalized Anxiety Disorder (GAD-7) and the Primary Care PTSD Screen for DSM-5 (PC-PTSD-5).

Background, Significance and Rationale

Background, Significance and Rationale

Coronavirus disease 2019 (COVID-19) has widely and rapidly spread around the world, overwhelming intensive care units and health care capacity, leading the World Health Organization (WHO) to declare a pandemic. According to the official website of the WHO1, more than 3 million people have been confirmed to have a COVID-19 infection, and over than 200,000 deaths have resulted from COVID-19 in almost every area or territories around the world1. To effectively cope with 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. Non-essential workers were required to stay at home and the shutdown of non-essential businesses are among the restrictions that influence the lives of millions across the globe. 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.

The outbreak of COVID-19 caused public panic and mental health stress. The rapidly changing information on COVID-19 and the increasing number of confirmed cases and death have elicited fear and anxiety about becoming infected. Isolated at home, people consume information that might be unreliable and unverified for many hours every day. The widespread use of social media and the extensive array (or sources) of information can increase confusion and worries which in turn increase fear and anxiety. Moreover, indirect exposure to 24-hours of television news and social media has a wide range of psychopathological consequences, of which Posttraumatic Stress Syndrome (PTSD) symptoms are the most common.2 A recent study3 conducted in China one month into the outbreak examined the prevalence of mental health problems in COVID-19 era and found a high rate of depression (48.3%), anxiety (22.6%) and a combination of depression and anxiety (19.4%) among 4,872 people. Furthermore, people with increased social media exposure were almost twice as likely to have depression and anxiety than people with less social media exposure. To date, more than 3 billion people are being asked to stay at home, which may lead to increased exposure to social media, likely resulting in widespread mental health problems among isolated individuals around the globe. Given the magnitude of the COVID-19 outbreak, its risk to physical and mental health, and the unique nature requiring to stay isolated, sheltered, at hospitals, or at home, an effective and timely response is essential to address the psychosocial needs associated with the ongoing exposure to social media, disease, death, and distress.

Among the general population, there are high-risk groups as elderly people, disabled individuals and people with previous exposure to trauma (e.g., people with military experience). Veterans are among the subgroups who are high risk for PTSD and other mental health problem. Furthermore, many veterans are reluctant to seek help, despite enduring symptoms, they avoid mental health care, or may wait years to decades before they seek help.4 Among reasons to avoid seeking help, patients report mistrust in mental health providers, being seen as weak or stereotyped as "dangerous/violent/crazy", and a belief that they are responsible for having mental health problems.5,6Applying strategies to reduce self-stigma and improve help seeking behavior among veterans may ameliorate impaired functioning and reduce risks for long-term psychiatric illness. Thornicroft7 showed that social contact is the most effective type of intervention to improve help-seeking behavior and stigma-related attitudes. Social contact involves interpersonal contact with a member of the group; While both direct, in-person social contact and indirect, video-based social contact have effectively improved attitudes toward mental illness, the latter can be implemented on a larger scale.8-10 Corrigan and colleagues11 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 COVID-19").
The overarching goal of this study is to examine the efficacy of an online, large-scale, brief video-based intervention in reducing fear and stress and improving help seeking behavior in relate to COVID-19.

Specific Aims and Hypotheses

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In a sizable randomized controlled trial (N=2,000), with pre-, post- and follow-up assessments the aim is to (1) determine whether video-based intervention reduce self-stigma and social media use and increase help-seeking behavior in relate to COVID-19 among people with military experience, and to (2) test the effect of the intervention in reducing symptoms of depression, anxiety and PTSD, that will be measured by Patient Health Questionnaire (PHQ-9) and Generalized Anxiety Disorder (GAD-7) and the Primary Care PTSD Screen for DSM-5 (PC-PTSD-5).

Hypotheses: That (1) the brief video is expected to have greater impact in reducing self-stigma, increasing help-seeking behavior and changing habits of social media use in relate to COVID-19 than a written vignette or control groups in comparison to pre-intervention and to non-video conditions, (2) the brief video is expected to have greater impact in reducing symptoms of depression and anxiety an PTSD.

Description of Subject Population

Sample #1

Specify subject population
US Adults with military experience
Number of completers required to accomplish study aims
2000

Projected number of subjects who will be enrolled to obtain required number of completers
2000
Age range of subject population
18-80

Gender, Racial and Ethnic Breakdown
It is expected the sample will roughly mirror the general *United States* adult population:
Anticipated gender distribution: 52% female, 48% male
Anticipated racial distribution: 79% white only, 13% African American only, 2% Asian only, 1% Native American, 5% 2+ races
Anticipated Hispanic Ethnic Distribution: 15% Hispanic, 85 % Non-Hispanic Description of subject population
Description of subject population
Participants recruited using Amazon Mechanical Turk (AMT) will be adults in the U.S. with military experience who are willing to complete an online experiment for a small financial reward.

Recruitment Procedures

Describe settings where recruitment will occur
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 persons to choose from a large number of tasks to perform, including completion of surveys, for 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 with military experience 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 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.
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?
Yes

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	Method of Ascertainment
Military experience and at least 18 years old	AMT requires respondents to be at least 18 and to have military experience
80 years old or younger	AMT settings will be used to exclude participants over 80 years of age
U.S. Residents	AMT settings will be used to limit responses to users in the United States

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

Study Criteria	Method of Ascertainment
Aged younger than 18	AMT requires respondents to be at least 18
No military experience	AMT requires respondents to have military experience

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 listed 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
The proposed research will examine the effects of video-based intervention in people with military experience. Participants will be randomly assigned to either a) video-based intervention featuring the personal story of a veteran who was deployed to Afghanistan and now suffering from **COVID-19 related symptoms**, and his straggles and barriers to care, (b) vignette intervention – a written description of the same personal story, (c) no-intervention control arm.

Qualtrics.com (the platform used for data collection) will automatically randomly assign each participant to one of the **three** arms.

The video-based intervention comprises of roughly 90-second video with a veteran describing his attitude towards COVID-19 before and after he was tested positive and his personal barriers to treatment and recovery, his personal experience with the use of social media, his fears and anxieties (i.e., sharing his/her own lived experience). The vignette, a written description of the aforementioned story, will deliver the same information, but without the social contact component that the video presents. The video/vignette will be provided at the day one. Before and after each intervention, a survey will be provided to all groups. In day 14, and day 30, a follow-up survey will be provided to all groups.
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-up (day 14 and day 30).
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 and day 30):

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.11 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 and day 30):

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.

In sum, the estimate time for day 1 (pre and post intervention) is 8 minutes for intervention groups and 6 minutes for control. The estimate time for each follow up is 5 minutes (day 14 and 30).

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.

The investigators of this research will only have access to the anonymous responses and associated demographic data of the respondents. They will not have access to any identifiable information of the respondents, and therefore will be unable to identify any individual respondent. When setting up the data collection procedures on Qualtrics.com, settings available from Qualtrics will be used to ensure that IP addresses will not be collected.
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 $3.30 in total for participating in the study ($1.10 for Day 1, $1.10 for the follow-up on Day 14, and $1.10 for the follow-up on Day 30), 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 $3.30). There are no bonus payments associated with this study.

References

References
References

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3. C Henderson, S Evans-Lacko, G Thornicroft. Mental illness stigma, help seeking, and public health programs. Am J Public Health, 103 (2013), pp. 777-780.
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7. Thornicroft G, Mehta N, Clement S, Evans-Lacko S, Doherty M, Rose D, Koschorke M, Shidhaye R, O'Reilly C, Henderson C. Evidence for effective interventions to reduce mental-health-related stigma and discrimination. The Lancet. 2016 Mar 12;387(10023):1123-32

8. Corrigan PW, Kleinlein P. The Impact of Mental Illness Stigma, On the Stigma of Mental Illness: Practical Strategies for Research and Social Change. American Psychological Association, Washington, DC. 2005.
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12. Berger, B. E., Ferrans, C. E., & Lashley, F. R. (2001). Measuring stigma in people with HIV: Psychometric assessment of the HIV stigma scale. Research in Nursing & Health, 24(6), 518-529.

Uploads

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