Protocol Title:
Meditation and Yoga for Heightened Anxiety related to COVID-19

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Protocol Number:
7987

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Research Area:
Anxiety, Mood, Eating & Related Disorders
Division:
Anxiety/PTSD/OCD

Expiration Date:
No Expiration

Contact Principal Investigator:
Brian Fallon, MD
Email: baf1@columbia.edu
Telephone: 646-774-8052

Co-Investigator(s):
Clair Bennett

Research Chief:
Roberto Lewis-Fernandez, MD

Annual Progress

Current Status of Study

Current Status of Study
Only data analysis is ongoing
Number of participants currently enrolled:
0
Is NYSPI-IRB the IRB of record? If No, specify the IRB of record and, if applicable, provide a copy of the most recent approval notice.
Yes
Confirmations:
✓ Confirm there have been no un-reported serious adverse events (SAEs)
✓ Confirm there have been no unapproved modifications
Total Number of participants enrolled to date:
256

Summary

Have there been any study findings, recent literature, or untoward events occurring here or at other sites in the past year which might affect the analysis of the safety, risks or benefits of study participation?
No

Confirm that all study staff with a significant role in the design or implementation of the human subject components of this study has completed required training in human research subject protections.
✓ Yes

Overall Progress

Approved sample size:
450
Total number of participants enrolled to date:
256
Number of participants who have completed the study to date:
256
Has the drop-out/withdrawal rate been significant?
Yes
There was sizeable dropout by week 2. Of the 256 who were randomized, by the end of the first two weeks, the drop-out rate was 49% for psychoeducation alone, 52% for psychoeducation plus meditation, and 69% for psychoeducation and Kundalini yoga (calculated based on the number of participants who completed at least one questionnaire by the end of the week 2). By the end of the treatment period in the study (week 8) the drop-out was 71% for psychoeducation alone, 72% for psychoeducation plus meditation, and 84% for psychoeducation and Kundalini yoga.
Comments / Additional Information
N/A

Procedures

To create the protocol summary form, first indicate if this research will include any of the following procedures

✓ Somatic Treatment or Intervention
✓ Internet-based Data Collection or Transmission

Population

Indicate which of the following populations will be included in this research

✓ Medically Ill Subjects
✓ Adults
✓ Adults over 50

Research Support/Funding

Will an existing internal account be used to support the project?
Yes
Describe internal account
This project will be supported by the miscellaneous research accounts in Columbia University and the RFMH
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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The global spread of COVID-19 is likely to have wide-ranging mental health consequences. As fear in our society increases, the ability of individuals to cope and to make rational well-informed decisions for themselves and for loved ones may become compromised. Anxiety may lead to increased despair, somatic symptoms, depression, suicidal thoughts, and interpersonal conflict with consequent increased use of health care resources. To allay one's fears, people may seek reassurance from an already over-burdened health care system. In the current context, this may have deleterious consequences for patients, healthcare workers, and

the broader community.

The primary purpose of this study is to determine whether heightened anxiety in the context of COVID-19 can be reduced through web-based interventions. While a certain level of anxiety is appropriate during a pandemic of infection that may have profound consequences to self and others, excessive anxiety can lead to impaired mood, thoughts, and behaviors. After confirming eligibility remotely, we will randomly assign participants to one of three on-line treatments: a) Meditation with psychoeducation; b) Kundalini Yoga with psychoeducation; and c) Psychoeducation alone. All 3 groups therefore will receive psychoeducational material about mental health care, but two of the 3 groups will also receive a mind-body therapy (mindfulness meditation or Kundalini Yoga). This study will recruit participants from throughout the United States.

Our research team is uniquely qualified to conduct this study given its expertise in anxiety disorders (esp illness anxiety and OCD) and infectious disease. Each person's study treatment is 8 weeks with a follow-up assessment at 3- and 6-months post-treatment. Our hope with this study is that all participants will experience a reduction in anxiety and improved psychological health as a result of participation.

The psychoeducation component received by all participants educates about the impact of anxiety on the body and how our thoughts, feelings, and behaviors can be modified to reduce anxiety. Kundalini Yoga consists of breathing, meditation, and stretching techniques. The guided meditation includes breathing and mindfulness training delivered online. We plan to assess the extent to which these two mind-body practices can augment the psychoeducation in reducing anxiety. The primary outcomes will be improvement in self-reported anxiety and in self-reported multisystem symptom severity. Secondary outcomes will assess cognitive complaints, depression, sleep, and fatigue.

This will be an on-line study. During this study, patients will be screened through an on-line process, review consent, and complete self-report questionnaires. 450 patients will be enrolled. Of these, 150 will be randomly assigned to kundalini yoga with psychoeducation, 150 will be assigned to mindfulness meditation with psychoeducation, and 150 will be assigned to psychoeducation alone. Assessments will be conducted weekly to 8 weeks; there will also be a 3- and 6-month follow-up by questionnaire. All participants at the end of the 8 weeks will be offered the option of receiving an additional 8 weeks of free access to meditation recordings through Journey meditation which provide guided meditation. For follow-up purposes, we will collect information on any/all treatments (e.g., psychopharmacological, psychotherapeutic, mind-body therapies) that participants have engaged in during the post-treatment phase to control for this at the analysis stage.

Should this study find evidence suggesting that either meditation therapy with psychoeducation and/or Kundlini Yoga with psychoeducation delivered remotely contribute additional benefit beyond psychoeducation alone in augmenting anxiety reduction, this would be a valuable and welcome research finding that would have broad public health implications as it provides patients in the time of a public health crisis with a beneficial new approach to addressing anxiety.

Background, Significance and Rationale

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In January 2020, the coronavirus disease 2019 (COVID-19) was declared a public health emergency of international concern by the World Health Organization. Since then, the number of cases has risen exponentially in the United States and world-wide, and the rapid spread of the virus has now been designated a global pandemic. The individual and societal costs of the pandemic are already wide-ranging, leading to substantial psychological burden even for those who have not been infected. A recent synthesis of psychological reactions to past infectious disease outbreaks indicated that anxiety and depression were among some of the most common symptoms experienced (Chew et al, 2020) . Other symptoms included somatic complaints, anger, irritability, grief, and post-traumatic stress.

In the current context, anxiety is likely to be one of the most prevalent symptoms due to increasing uncertainty concerning health outcomes, contamination fears, and financial and occupational instability, as well as worry about the broader social and economic consequences. Approximately 25 to 33% of the population are likely to experience high levels of anxiety and worry, based on research from similar global pandemics (Bults et al, 2015; Lau et al 2008). Individuals with pre-existing medical and mental health issues may be at greater risk.

The primary purpose of this study is to determine whether heightened anxiety in the context of COVID-19 can be reduced through web-based interventions. While a certain level of anxiety is appropriate during a pandemic of infection that may have profound consequences to self and others, excessive anxiety can lead to impaired mood, thoughts, and behaviors. After confirming eligibility remotely, we will randomly assign participants to one of three on-line treatments: a) Meditation with psychoeducation; b) Kundalini Yoga with psychoeducation; and c) Psychoeducation alone. All 3 groups therefore will receive psychoeducational material about mental health care, but two of the 3 groups will also receive a mind-body therapy (mindfulness meditation or Kundalini Yoga). This study will recruit participants from throughout the United States.

Our research team is uniquely qualified to conduct this study given its expertise in anxiety disorders (esp illness anxiety and OCD) and in infectious disease. Each person's study treatment is 8 weeks with a follow-up assessment at 3- and 6-months post-treatment. Our hope with this study is that all participants will experience a reduction in anxiety and improved psychological health as a result of participation.

The psychoeducation component received by all participants educates about the impact of anxiety on the body and how our thoughts, feelings, and behaviors can be modified to reduce anxiety. This psychoeducation component was developed in collaboration with Dr. Jill Newby at the University of New South Wales in Australia. Dr. Newby's on-line cognitive behavioral program ("ThisWayUp") for anxiety production includes psychoeducational handouts. We extracted material on stress and anxiety reduction and on healthy habits from these psychoeducational handouts.

Kundalini Yoga consists of breathing, meditation, and stretching techniques. Recent studies suggest that Kundalini Yoga can be helpful in reducing anxiety. One study of patients with Generalized Anxiety Disorder (GAD) found that an 8 week study of KY compared to "treatment as usual with cognitive techniques" led to reduced anxiety and fewer somatic symptoms (Gabriel et al 2018). Another non-randomized single arm study among patients with GAD reported that CBT when combined with Kundalini Yoga led to significant improvements in state and trait anxiety, depression, panic, sleep, and quality of life

(Khalsa et al, 2015). A most recent randomized clinical trial reported that KY performed better than the relaxation response therapy among patients with OCD (Shannahoff-Khalsa 2019). The KY practice to be used in this study was promulgated and disseminated by one of the best known teachers of KY in the Western Hemisphere, Gurucharan Singh Khalsa (Phd). Dr. Khalsa has been the leading international director of training for Kundalini Yoga for 40 years and is a well-known author, lecturer and researcher on KY. Dr. Charles Alexander (MD) studied with Dr. Khalsa; Dr. Alexander is a certified instructor in this method has had over 500 hours of training in KY. Dr. Alexander teaches the KY approach by video and by audio in this arm of the treatment study. Dr. Khalsa also provides video instruction in the beginning phase of the study.

Mindfulness-based meditation interventions have robust research demonstrating mild-moderate effect sizes in reducing anxiety and depression (Blank et al, 2018). The guided meditation in this program includes breathing and mindfulness training delivered through a meditation online provider (called Journey). A recent publication using this specific meditation provider compared to a podcast control group (Basso et al 2019) demonstrated that 8 weeks of meditation therapy led to significantly greater improvement in mood, anxiety, and cognition (attention, working memory, and recognition memory).

We plan to assess the extent to which these two mind-body practices can augment the psychoeducation in reducing anxiety. The primary outcomes will be improvement in self-reported anxiety and in self-reported multi-system symptom severity . Secondary outcomes will assess cognition, depression, sleep, and fatigue.

This will be an on-line study. During this study, patients will be screened through an on-line process, review consent, and complete self-report questionnaires. 450 patients will be enrolled. Of these, 150 will be randomly assigned to kundalini yoga with psychoeducation, 150 will be assigned to mindfulness meditation with psychoeducation, and 150 will be assigned to psychoeducation alone. Assessments will be conducted weekly to 8 weeks; there will also be a 3- and 6-month post-treatment follow-up by questionnaire. All participants at the end of the 8 weeks will be offered the option of receiving an additional 8 weeks of access to free online meditation recordings through Journey meditation which provides guided meditation.

Should this study find evidence suggesting that either meditation therapy with psychoeducation and/or Kundlini Yoga with psychoeducation delivered remotely contribute additional benefit in augmenting anxiety reduction, this would be a valuable and welcome research finding that would have broad public health implications as it provides patients in the time of a public health crisis with a beneficial new approach to addressing anxiety.

Specific Aims and Hypotheses

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Hypothesis:
Our expectation is that many patients will benefit in this study, regardless of the treatment received, as everyone will be receiving psychoeducation. Our primary hypothesis: Among participants with heightened anxiety in the context of an infection pandemic (COVID-19), augmentation of psychoeducation with Kundalini Yoga or Meditation will lead to a greater reduction in anxiety and in severity of multi-system

symptoms than treatment with psychoeducation alone.

SPECIFIC AIMS

Aim 1: Test whether Kundalini Yoga with psychoeducation results in a significantly greater reduction in anxiety and multi-system symptom severity and in improvement in secondary outcomes (e.g., depression, sleep, illness anxiety, fatigue, cognition) compared to psychoeducation alone

Aim 2: Test whether a mindfulness meditation practice with psychoeducation leads to a significantly greater reduction in anxiety and multi-system symptom severity and in improvement in secondary outcomes (e.g., as above) compared to psychoeducation alone

Aim 3: To assess whether treatment outcomes are moderated by COVID-19 related variables (e.g., health/COVID exposure status, impact on job/school/financial stability) and personal variables (e.g, prior health status, substance use, intolerance of uncertainty, social support network, spirituality/religiosity)

Aim 4: To assess at the follow-up at month 3 whether patients have continued with the meditation practice and whether gains observed at week 8 have been sustained.

Aim 5: To assess whether there is a difference in both primary and secondary outcomes between the Kundalini Yoga and the meditation treatment groups.

Description of Subject Population

Sample #1

Specify subject population
Individuals with heightened anxiety
Number of completers required to accomplish study aims
270
Projected number of subjects who will be enrolled to obtain required number of completers
360
Age range of subject population
18-70

Gender, Racial and Ethnic Breakdown
Our Estimates are based on nationwide surveys of meditation practice conducted by the Pew Research Center
https://www.pewforum.org/religious-landscape-study/frequency-of-meditation/#demographic-information

Based on the Pew publications of the U.S. Population, we anticipate the following gender and racial/ethnic

group representation
Gender: 50% women, 50% men
Racial/ethnic: 60% Caucasian, 15% Black, 18% Latino, and 7% other
Description of subject population
This is a study for patients age 18-70 (male and female, all ethnic groups) who report heightened Anxiety related to COVID-19. Our target enrollment is 360 individuals.

Recruitment Procedures

Describe settings where recruitment will occur
1. Notices will be placed on Columbia's Recruit Me website and on our Columbia Lyme website.
2. The study will also be advertised on Proof pilot's website.
3. The study will also be posted on ClinicalTrials.gov

Media. ProofPilot, and Hokku PR (ProofPilot's PR agency) will reach out to selected nationwide online press to alert them that the study is open for enrollment. They will use NYSPI IRB-approved press releases to provide key talking points for the study and carefully guide the journalist to cover the study launch without biasing outcomes or misrepresenting the study purpose. Press to be considered are health and wellness journalists at Psychology Today, Washington Post, New York Times, CNN, CNBC, USA Today, and the Wall Street Journal among others. The NYSPI IRB-approved press release will also by syndicated across PR Newswire.

Social Media Referrals. We will design social media posting that can be shared on Facebook, Twitter, and Reddit. The share to these platforms includes the study title, main image and tagline. These posting will all be NYSPI IRB approved.

How and by whom will subjects be approached and/or recruited?

1. Email notices will be sent to primary care medical clinicians in areas of the country heavily affected by COVID-19 for referral of patients to the study. proofpilot and Columbia website for recruitment. Prior to sending email notices to clinicians, the notice will be submitted to the IRB for approval.

2. Physician and public health organizations will be notified about the availability of this study (e.g, CDC, IDSA).

3. Leaders in faith communities will be contacted to inform them of this study.

4. Social media postings

5. Press coverage (through Columbia, NYSPI, or ProofPilot connections).
How will the study be advertised/publicized?
Same as above.
Do you have ads/recruitment material requiring review at this time?

Yes
Does this study involve a clinical trial?
Yes
Please provide the NCT Registration Number
NCT04386291

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
Adults with anxiety related to COVID-19
Create or insert table to describe the inclusion criteria and methods to ascertain them

Inclusion Criteria	Ascertainment Method
1. Heightened Anxiety triggered or exacerbated by COVID-19	1. Self-report
2. Anxiety is at least mild- moderate in severity	2. GAD-7 score of 7 or greater
3. Age 18-70, male or female	3. Self-report
4. English speaking and living in the U.S.	4. Self-report
5. Consistent access to a smart phone, tablet or computer with internet.	5. Self-report

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

Exclusion Criteria	Ascertainment Method
1. Current or past episode of psychosis or bipolar disorder	1. Self-report
2. Substance abuse within the last 6 months	2. Self-report
3. Pain disorder treated with opiate-based medication	3. Self-report
4. Current severe depression	4. Score of 20 or higher on PHQ8
5. Individuals with physical disability that might make study	5. Self-report

participation difficult	
6. Unwillingness to complete questionnaires on-line, dedicate 30 minutes daily to meditation and/or stretching, or refrain from starting other new mind-body therapies during the study	6. Self-report
7. Individuals with a current daily practice of Kundalini yoga or meditation	7. Self-report
8. Individuals unwilling to be contacted for follow-up at 3-months and at 6-months	8. Self-report
9. Individuals unwilling to accept push notifications to their smart phone or computer	9. Self-report
10. Individuals with confirmed or suspected COVID-19 (including recovered cases) based on a positive test result, or CDC surveillance guidelines which require either: a) one of the following: cough, shortness of breath, or difficulty breathing; or b) two of the following: fever, chills, rigors, myalgia, headache, sore throat, new olfactory and taste disorder. (As per CDC guidelines, if an alternative explanation is more likely - based on patient history or medical evaluation - symptoms will not be considered suspicious for COVID-19).	10. Self-report
11. Individuals unwilling to provide the name and contact information of an individual in the case of emergency	11. Self-report
12. Pregnant women or women trying to become pregnant in the next 8 weeks.	12. Self-report
13. Individuals with an unstable medical illness over the last 12 months	13. Self-report
14. Unwillingness to affirm sufficiently good medical health to safely participate in breathing exercises (e.g., 120 breaths per minute) and mild stretching exercises	14. Self-report
15. Lifetime history of suicide attempt, PTSD or psychiatric hospitalization	15. Self-report
16. Lifetime history of cardiac disease	16. Self-report
17. History over the last 12 months of lightheadedness, dizziness, vertigo, loss of balance	17. Self-report
18. Suicidal ideation with intent (i.e., suicide plan) in the past 6 months	18. Self-report

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
1. Patients will be asked to provide either a phone number or email address prior to entering the study portal on proofpilot. Patients will then be screened using our screening questions which will be provided on-line to prospective participants through the Proofpilot. Questions will include demographics, psychiatric, medical and symptom history, current meditation or yoga practices. No identifying information will be asked during this initial screening process.

2. Proofpilot will automatically determine whether the applicant meets criteria for inclusion and exclusion. Those who are eligible will then be directed to the next web page showing the study consent. Those who are not eligible will be advised to seek meditation and/or yoga in their community. If deemed eligible, patients will then enter a password to complete their account creation.
Describe Study Consent Procedures
After patients complete screening questions, they will be invited to read the consent form and then confirm decision to participate in the study as noted below.

Patients will be provided with an email address through which they can send any questions about the study to the study research coordinator (Ellen Brown) prior to completing the consent process (or after consent during the course of the study.) Our study staff will not be assessing eligibility; this will be based on the algorithm.

After the patient has read the consent document, he/she will be asked to check three boxes on the page indicating: a) that he/she understands the study's purpose, methods, and risks and benefits as outlined in the consent; b) that the participant will be randomly assigned to one of three groups – meditation with psychoeducation, Kundalini yoga with psychoeducation, or psychoeducation alone; and c) that the patient is willing to participate in the study.

After checking all three of these boxes, the participant will be asked to enter the password they created to log into proofpilot and that will complete the consent procedure. No electronic signature is being collected. We are using a button consent option with password confirmation.
Indicate which of the following are employed as a part of screening or main study consent procedures
✓ Consent Form

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
We are requesting a waiver of documentation of consent for the online consent procedure. There is no signature on the consent form therefore it would not link the subject and research data at all.

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
Consent is obtained through Proofpilot. The participant will not speak with the investigators.

Should questions arise about the study, these will be direct to the study coordinator Ellen Brown.

Study Procedures

Describe the procedures required for this study
Recruitment
Interested participants will be directed to Proofpilot's website from recruitment materials or from the websites that educate others about this study. Interested individuals will be directed to screening through the website.

Screening
Individuals will fill out a demographic form as well as a screening questionnaire.

Consent Procedures
If deemed eligible based on the answers related to I/E criteria, participants will be notified to complete informed consent on Proofpilot's website. Individuals who have questions about the study can email the study coordinator. Once consent is completed, they will then be asked to watch a video to encourage their full participation throughout the 8 weeks. They will then complete the baseline set of assessments prior to randomization.

If deemed ineligible to participate, participants will be encouraged to identify a yoga or meditation group in their community. If deemed ineligible due to suspected COVID-19 symptoms, patients will be advised to contact their local health care provider. Patients who score in the severe range for depression and who are excluded from participation will be advised to contact a local health provider for further evaluation of depression.

Study Procedure

Outcome Measures and other assessments. All participants will complete the baseline self-report questionnaires which assess current symptoms, impact of COVID-19, and additional medical and psychosocial history (including lifetime stressors). The full battery of Primary and Secondary outcome measure battery and COVID Follow-up queries will be conducted at baseline, and weeks 4, 8 (primary outcome), and at 3- and 6-months post-treatment. On a biweekly basis to week 8 (primary outcome time point), patients will complete the primary outcome measures and will be asked about their health status and any change in medication or treatment. In addition, on a daily basis, patients randomized to meditation or Kundalini Yoga will be asked to complete a daily log of their daily meditation/yoga practice.

1. Primary Outcome Measures

1. Symptom-based measures. GAD-7 (generalized anxiety); Whiteley-8 (health anxiety)

Secondary Outcome Measures

1. Symptom-based measures:

    - PROMIS sleep disturbance
    - PHQ8 (depression)
    - SSS-8 (somatic symptoms)
    - ERQ (emotion regulation)
    - PSS-10 (stress)
    - Brief hypervigilance scale

2. Health status: Overall Health in general (1 item)
3. Cognition: Neuro-QOL - Applied Cognition (8 items)

Moderators

Selected demographic variables
COVID-19 Exposure and related variables ("CRISIS" survey)
Intolerance of Uncertainty
Mental Health History
Prior Experience with Mind-body practices
Personal Religiosity or Spirituality (Importance; Identification)

Randomization (1:1:1). Participants will be randomly assigned to one of three groups: a) Meditation (using Journey meditation) with psychoeducation; b) Kundalini Yoga (provided through an on-line video program) with psychoeducation; or c) psychoeducation alone.

Incentive to Participate.

a). All patients receive psychoeducation and tools to help decrease anxiety.

b) Two of three patients also receive assignment to meditation or Kundalini Yoga.
c) All participants who complete the initial 8 weeks of the study (treatment phase) will receive a free 8-week subscription to online meditation recordings via Journey meditation.

Description of Treatments

a. *Psychoeducation*. With the generous intellectual support of Dr. Jill Newby and the ThisWayUp Cognitive Behavioral team at the University of New South Wales (Australia), we have adapted a set of four psychoeducation 3-4 page handouts to be given to all study participants that are designed to reduce anxiety (see appendix). Every 2 weeks, a new handout will be sent out (baseline and weeks 2, 4, 6). The topics include: a) Education about health anxiety and the body's fight/flight response; b) Education about the negative effects of attention and checking behaviors (with a specific focus on internet checking); c) Healthy thoughts and unhelpful thinking patterns; and d) Healthy habits (includes info on sleep and exercise). All participants (in each of the groups) will receive introductory material that explains the purpose of the psychoeducation tools and how they should be used. This material will also remind the participant of the procedures for the duration of the study (e.g., self-report questionnaire completion at baseline, 2, 4, 6, and 8 weeks and at the 3- and 6-month post-treatment follow-ups).

b. *Meditation* (via Journey). This meditation aims to train the mind for a healthier lifestyle through a 15 minute daily guided audio meditation delivered online. The group randomized to meditation will receive introductory material that explains the purpose and use of the psychoeducation tools and introduces the meditation daily practice with guided breathing. This material will also remind the participant of the procedures over the course of the study (e.g., daily log completion, self-report questionnaire completion at baseline, 2, 4, 6, and 8 weeks and at the 3- and 6-month post-treatment follow-ups). They will then be directed to a link to the meditation video. Participants will be provided with the meditation program after completing the introductory/baseline questionnaires. Each day, they will participate in 15 minutes of meditation.

c. *Kundalini Yoga*. Kundalini Yoga incorporates a daily practice of movement (stretching and hand movements), guided breathing, and meditation. The group randomized to Kundalini Yoga will receive introductory material that explains the purpose and use of the psychoeducation tools and introduces the daily practice of Kundalini yoga. This material will also remind the participants of the procedures over the course of the study (e.g., daily log completion, self-report questionnaire completion at baseline, 2, 4, 6, and 8 weeks and at the 3- and 6-month post-treatment follow-ups). After the initial introduction, participants will watch a 10 minute video guiding them in various bodily stretching that precedes each of the Yoga and Meditation practices. They will then watch videos demonstrating both the daily breathing exercise and the meditation. In addition, during the 8 weeks of the study, participants will watch weekly videos that address a different aspect or reinforce aspects of Kundalini Yoga and meditation. They will also be prompted to continue to conduct the Breathing and Meditation each day.
Stretching (brief description): Guided in the video, this includes about 9 minutes of gentle stretching movements of the arms and body. This can be done standing or in a chair if more comfortable.
Kundalini Yoga (The initial Kundalini session is as follows)
This lasts about 8 minutes. It is a directed breath. Sitting comfortably with a straight spine in a chair or on the floor, as desired. The subject is instructed to perform a short repetitive breath named Breath of Fire. Breath of Fire is characterized as an active exhale, a pulse of the abdomen in towards the spine, which forces air from the lungs. This is than followed by a relaxation of the abdominal muscles and diaphragm. As

the abdomen and diaphragm relax air enters back into the lungs only to be exhaled again by the pulse of the abdominal muscles. This progresses at an approximate rate of one breath per second but, when done correctly, it does not lead to hyperventilation and, in fact, it can be performed for extended periods of time. In this study, the breath is performed with the thumb tip touching first the tip of the index finger while the hands are rotating at the wrists. The rotation is a small movement such that the right hand is rotating clockwise while the left rotates counter-clockwise. This causes the hands to approach each other at the bottom of the rotation and to depart from each other at the top of the rotation. If there is too much pain in the wrist joints to do this comfortably, the hand rotation can be done as a visualization. After one and a half minutes, while continuing the hand rotation, the thumb is switched so as to touch the tip of the middle finger for a minute and a half than, sequentially, the other fingers until all have spent an equal amount of time touching the thumb tip. When all this is completed, the hands are cupped and brought together such that the fingertips of one hand are in contact with the same fingertips of the opposite hand. After one minute the two cupped hands are separated so as to create a space of about 6 inches between the tips of the fingers. After one minute more, the subjects move on to the guided meditation.

Guided Meditation. This lasts 11 minutes. It is composed of words spoken over a musical background. In this meditation the subjects are guided to picture a healing force or light, a positive energy field, circulating around and within and through themselves. When this force comes in contact with areas that are troubled or painful, subjects are instructed to visualize the distress as being transformed such that healing takes place.They will complete the 25 minutes of stretching/meditation each day. Each week they will watch a new informational talk on Kundalini yoga. Participants will be asked to maintain a meditation log throughout the 8 weeks. They will be asked to record the number of minutes of meditation and stretching as well as any discomfort they experienced. They will also fill out questionnaires at weeks 2, 4, 6, 8 and at 3- and 6-months post-treatment.

Study Drop-outs. Participants are free to drop-out of the study at any time. We will ask participants in the consent form to complete a set of assessments at the time point that they discontinue from the study and also complete a questionnaire indicating the reason for dropping out.

3-Month and 6-Month Follow-ups. All participants will be asked to complete a follow-up set of assessments at 3- and 6-months post-treatment which will allow us to determine whether treatment gains at week 8 have been sustained and whether the meditation or yoga practice has been continued. The study will not impose any restrictions on the participants after week 8. In other words, participants are then free to pursue other interventions if they wish.

After a study is closed to new enrollment, a feedback questionnaire will be sent to all study participants.The feedback questionnaire consists of two parts:
- the Treatment Satisfaction Questionnaire (3 questions) and
- 6 questions about participant's decision to discontinue the study.

Overall, it takes less than 3 minutes to complete the questionnaire. Participants may choose not to answer any of the questions. Neither of the questions requires to disclose any personal information.

Contact with our research team:

a. For study-related questions, participants will be able to reach our study coordinator through Proofpilot or through email to our study coordinator

b. For clinical emergencies, as described in the consent form, participants should go to the nearest emergency room or be evaluated by their current doctor.

c. Should the clinical assessment of depression after randomization indicate a rating in the severe range, an automatic email will be sent to the study coordinator and members of the team notifying them of the participant's high score. The study coordinator will then email the participant and recommend an evaluation by a local mental health provider. The patient will be asked to complete a follow-up depression rating 2 weeks later. If the score again falls in the severe range, one of our study clinicians will attempt to contact the patient by email or phone to recommend evaluation by a local mental health provider and to discuss withdrawal from the study. Withdrawal from the study will be determined according to the clinician's judgement after speaking with the participant, and assessing the costs/benefits to the participant of continuing with the intervention. This does not preclude the clinician from also making referrals or recommendations regarding additional treatment.

You can upload charts or diagrams if any

Criteria for Early Discontinuation

Criteria for Early Discontinuation

Participants who develop severe depression during the course of this study that persists on the PHQ8 measure for 2 consecutive assessments will be discontinued from the study if appropriate based on clinical judgement. The patient will be contacted by one of the study physicians either by phone (or email). During this contact the physician will recommend referral to a local mental health provider. The study physician will speak with the participant at this time to determine whether it is in the best interests of the participant to remain in or be withdrawn from the study. Significant worsening of depression will be operationalized as a PHQ8 score (20 or higher) that falls in the severe range on 2 consecutive 1-week ratings.

Assessment Instruments

Create a table or give a brief description of the instruments that will be used for assessment

Measure	# of items	Screen	Baseline	Week 2	Week 4	Week 6	Week 8	3-month FU	6-month FU
COVID-19 exposure/status	2	X							
CRISIS Survey Baseline and Follow-up 3.0	10-30		X	X	X	X	X	X	X
GAD-7	7	X	X	X	X	X	X	X	X
Whiteley 8	8		X	X	X	X	X	X	X
SSS-8	8		X		X		X	X	X
PROMIS Sleep	4		X		X		X	X	X

Disturbance									
Emotion Regulation Questionnaire	10		X		X		X	X	X
Neuro-QOL - Applied Cognition	8		X		X		X	X	X
PHQ-8	8	X	X		X		X	X	X
Brief Hypervigilance Scale	5		X		X		X	X	X
Intolerance of Uncertainty Scale	12		X		X		X	X	X
Perceived Stress Scale	10		X		X		X	X	X
Social Support	3		X						
Religiosity	2	X							
Meditation Practice Log				X	X	X	X	X	X
Medical Utilization			X				X	X	X
Current Pharmacotherapy			X	X	X	X	X	X	X
Current Psychotherapy			X	X	X	X	X	X	X
Current other Mind-Body Tx			X	X	X	X	X	X	X
Demographics		X							
Psychiatric and Medical History			X						
Treatment Credibility/Expectancy	4			X					
Treatment Satisfaction	2						X		

Please attach copies, unless standard instruments are used

Research Related Delay to Treatment

Will research procedures result in a delay to treatment?
Yes
Maximum duration of delay to any treatment

There is a delay in receiving the mind-body therapy among those randomized to psychoeducation alone. However, the psychoeducation component is given to all participants and therefore there is no delay due to research procedures. We anticipate psychoeducation does confer some benefit as it includes valuable information about ways to reduce anxiety that are drawn from the CBT courses in the ThisWayUP courses from New South Wales University. In fact, this is why all groups will be receiving psychoeducation. Our

goal is to determine whether meditation and/or Kundalini Yoga confer additional benefit on top of that obtained from the psychoeducation. Our answer is that because all participants are receiving a therapeutic modality that should confer some benefit, we do not believe there is a delay in starting treatment.

Note on Psychoeducation: Psychoeducation appears to be an effective intervention for anxiety/depression and psychological distress according to two recent reviews (Donker, Griffiths, Cuijpers, & Christensen, 2009; Rodrigues et al., 2018). Donker et al. (2009) concluded that 'brief passive psychoeducational interventions' in particular may prove effective in reducing symptoms. Further, in a recent study conducted by Newby and colleagues (2018) examining online interventions for health anxiety, the authors found medium and significant reductions on health anxiety, generalized anxiety, depression and disability in the psychoeducation control group. A similar methodology to the current study was employed using 2-4-page fact sheets on anxiety-related topics delivered biweekly to study participants.

Maximum duration of delay to standard care or treatment of known efficacy

There is no delay as all participants will be receiving treatment.

All participants in this study will be able to continue during the study with whatever treatment they had been receiving prior to the start of this study. All participants are asked to not start new treatments during the first 8 weeks of the study. However, if medically or psychiatrically indicated, patients can start new treatments. We ask all patients to record any new treatments received. After the 8 weeks, participants can pursue other treatments as they wish; as a gift for completing our study, all participants will be offered a free subscription to Journey meditation recordings.

For follow-up purposes (3- and 6-months), we will collect information on any/all treatments (e.g., psychopharmacological, psychotherapeutic, mind-body therapies) that participants have engaged in during the post-treatment phase to control for this at the analysis stage.

There is no delay as a result of completing study questionnaires as these can be done on the same day as starting treatment.

Maximum duration of delay to standard care or treatment of known efficacy:
8 weeks

Treatment to be provided at the end of the study

All participants will be offered 8 weeks of Journey meditation at no cost to them.

Clinical Treatment Alternatives

Clinical treatment alternatives
Individuals do not have to participate in this study in order to obtain guidance in meditation or yoga

stretching. Both therapeutic modalities are available elsewhere. Individuals who wish to receive private treatment will be advised to consult with practitioners in their area.

Risks/Discomforts/Inconveniences

Risks that could be encountered during the study period
1. Quiet Meditation can sometimes lead to distress among individuals with a prior trauma history as they may re-visualize or remember the trauma during the quiet meditation.

2. The self-report questionnaires may lead to psychological distress among some individuals.

3. Stretching or postures may lead to discomfort.

4. Individuals are asked to not start new treatments during the course of this study. For patients who may wish to start an optional treatment, the 8 week delay in starting a new treatment may result in delay in receiving a potentially beneficial optional treatment.

5. Treatments in this study may not reduce symptoms of anxiety. There is also the potential risk that symptoms may worsen, because meditation and psychoeducation can increase awareness of body sensations, thoughts and feelings which people may find to be unpleasant.

Describe procedures for minimizing risks
1. Patients can stop the self-report questionnaires, postures, meditation or any aspect of the psychoeducation component of the study at any point or if distress is excessive

2. Participants whose PHQ8 scores on the 8 item scale indicate severe depression will be emailed and advised to seek mental health consultation. Participants who have a rating of "severe" on the PHQ8 for 2 consecutive assessments will be contacted by a study physician, advised to seek mental health consultation, and if deemed appropriate by the study clinician, withdrawn from the study.

3. Participants will be given a way to contact the study coordinator through ProofPilot. For emergencies, participants are advised in the consent form to go to their local emergency room or health care provider.

4. If discomfort arises during stretching or postures, patients will be told they can stop at any point

5. If a treatment is recommended by a physician as medically necessary, then that treatment is allowed - the participant merely needs to notify us of this change.

Methods to Protect Confidentiality

Describe methods to protect confidentiality
All data collected on the ProofPilot Platform in this online clinical trial is stored in an encrypted manner using Google's cloud hosting services. All of the participant medical information and research data will be kept confidential to the extent permitted by law. There are legal advocacy organizations that have the authority under State law to access otherwise confidential subject records, but they cannot re-disclose this information without a participant's consent. Any research data transmitted or stored electronically will use a number assigned to the participant, not the participant's name. Although the information provided by the participant may be shared in a deidentified manner with researchers who are not part of our University, their private identifying information (such as name, address, date of birth, or any other personal information that could be used to identify the participant) will not be released at any point.

Google is a cloud hosting company - meaning that data is not housed on one individual server, but spread across many - increasing physical security. ProofPilot is housed on multiple physical servers reducing the potential for a server outage to cause any issue with uptime or data loss. We also backup the material on a near real time basis and geolocate them in the case of a full out data loss in one location.

For more information, read the included Proofpilot White Paper on Security, Privacy, and Ethics.

In regards to patient/researcher communication, any emails sent from the study team to participants will be sent securely using '#encrypt' which was recommended by PsyIT.
Will the study be conducted under a certificate of confidentiality?
No

Direct Benefits to Subjects

Direct Benefits to Subjects
This study may or may not directly benefit participants.
However it is our hope that participation will allow us to evaluate two widely used meditation techniques to determine whether they help to reduce symptoms of illness anxiety. It is hoped that the knowledge gained in this study will be of benefit to patients suffering from illness anxiety related to COVID-19.

Compensation and/or Reimbursement

Will compensation or reimbursement for expenses be offered to subjects?
No

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References

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Uploads

Upload copy(ies) of unbolded Consent Form(s)
Upload copy(ies) of bolded Consent Form(s)
Upload copy(ies) of recruitment materials/ads to be reviewed
Upload copy(ies) of the HIPAA form
HIPAA Waiver-alteration of consent_2020-04-21_CB.pdf
HIPAA consent_2020-04-24.pdf
Upload any additional documents that may be related to this study
Post_Study_Feedback_Questionnaire_4.6.2021.pdf

Statistician	Data preparation and analysis is performed by a research scientist for the team.
Study Objectives	The primary purpose of this study is to determine whether heightened anxiety in the context of COVID-19 can be reduced through web-based interventions. This randomized clinical on-line study will examine whether a daily practice of meditation or Kundalini Yoga with anxiety reduction training leads to a greater reduction in anxiety than anxiety reduction training alone.
Primary endpoint	Week 8 evaluation.
Study Design	This randomized on-line study is for individuals with anxiety and distress triggered by COVID-19 who have not yet been infected with the novel corona virus. The primary study goal is to examine the extent to which anxiety can be reduced through the use of on-line training programs. All participants will receive Anxiety Reduction Training using cognitive-behavioral methods known to be helpful in reducing stress, anxiety, depression, and insomnia. In addition, two-thirds of participants will be randomly assigned to receive training in either Kundalini Yoga (KY) or mindfulness meditation. The investigators will assess the degree to which each of these training programs lead to reduced stress, improved well-being, decreased multisystem symptoms, enhanced mood, and reduced cognitive complaints. Participants will complete self-report assessments at 2-week intervals during the 8 weeks of the acute phase of the study and then again 3- and 6-months later. For details see PSF.
General Study Population	See PSF respective section
Inclusion-Exclusion Criteria	See PSF respective section
Study Assessments	See PSF respective section
Sample size	The study enrollment was closed in 2022 with a sample size of 256.
Randomization	Randomization will be a simple allocation with 1:1:1 ratio. Participants will be randomly assigned to one of three groups: a) Meditation (using Journey meditation) with psychoeducation; b) Kundalini Yoga (provided through an on- line video program) with psychoeducation; or c) psychoeducation alone.
Primary aim#1	Aim 1: Test whether Kundalini Yoga with psychoeducation results in a significantly greater reduction in anxiety and multi-system symptom severity compared to psychoeducation alone.
Primary aim #2	Aim 2: Test whether a mindfulness meditation practice with psychoeducation leads to a significantly greater reduction in anxiety and multi-system symptom severity compared to psychoeducation alone.
Secondary aims and Exploratory goals:	Aim 3: To assess whether treatment outcomes are moderated by COVID-19 related variables and personal variables. Aim 4: To assess at the follow-up at month 3 whether patients have continued with the meditation practice and whether gains observed at week 8 have been sustained. Aim 5: To assess whether there is a difference in both primary and secondary outcomes between the Kundalini Yoga and the meditation treatment groups.

Timing of Analysis	Analysis will be performed after the study is stopped for enrollment and a year after to make sure that all participants have finished their participation.
Analysis Population	We conduct analysis of a change score between baseline and week 8 for those who were randomized into one of the study arms and completed active treatment phase.
Missing Data	Missing data is treated as missing at random
Interim Analyses and Data Monitoring	There is no interim analysis for the protocol.
Primary aim#1 analysis	To investigate whether Kundalini Yoga with psychoeducation results in a significantly greater reduction in two primary outcome measures compared to psychoeducation alone, we will compare two groups of completers using one-sided t-test. P-value and estimation parameter value will be provided.
Primary aim#2 analysis	To investigate whether mindfulness meditation practice with psychoeducation leads to a significantly greater reduction in two primary outcome measures compared to psychoeducation alone, we will compare two groups of completers using one-sided t-test. P-value and estimation parameter value will be provided.