Remotely Delivered Programs Targeting COVID-19 Stress-Related Depression and Substance Use

NCT04595084

Informed Consent Form

Version Date: October 13, 2021

CHA Cambridge Health Alliance	**INFORMED CONSENT AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH**

We try to make this form easy to understand. But it may have words or ideas that are not clear to you. Please ask a member of the study team to explain anything you do not understand. You may take this form home with you to discuss with family or friends before you decide whether to be in this research study.

Study Title: Remotely Delivered Programs Targeting COVID-19 Stress-Related Depression and Substance Use

Your name (Participant):	**Today's Date:**

Not including this study, are you taking part in any research now? ☐ Yes ☐ No

Name of Principal Investigator: Zev Schuman-Olivier, MD; Carl Fulwiler, MD, PhD

Name of Co-Investigator(s): Phil Wang, MD; MD; Richa Gawande, PhD; Todd Griswold, MD; Mark Albanese, MD; Benjamin Cook, PhD; Timothy Creedon, PhD; Ellie Grossman, MD; Christian Webb, PhD; David Almeida, PhD; Jackie Mogel, PhD; Christina Luberto, PhD

Consent form version date or number: Version 7.5, October 13, 2021

Name and telephone number of study contact to call with questions:
Gabriella Conversano, Research Coordinator (857-270-0666, resiliencestudy@challiance.org)

CHA IRB Number: CHA-IRB-1141/05/20	**Study Sponsor(s):** NIH/NCCIH

Key Information

- You are invited to take part in a study called “Remotely Delivered Programs Targeting COVID-19 Stress-Related Depression and Substance Use”
- Taking part in this study is voluntary. You have the choice to take part or not. You may leave the study at any time for any reason.
- You will be asked to participate in the study for 24 weeks. You will be asked to complete surveys before beginning the study, and then again at 4, 8, 12, 16, 20 and 24 weeks. You will also be asked to complete monthly computerized interviews throughout the 24-week study. You may also be asked to complete saliva sample collections at various timepoints if you participate in an optional sub-study.
- You will be randomly assigned to receive support from one of several programs: online groups, internet programs, and/or supportive calls at home. These programs aim to help you feel less isolated and more supported.
- You may not benefit from this program. If you are randomly assigned to participate in a group, you may have moments where you feel stressed, embarrassed, or anxious due to being in a group. You may spend extra time learning stress, anxiety reduction, and depression prevention techniques and be asked to practice skills at home between groups. You may have physical discomfort from gentle movement in groups. Despite strong efforts to maintain your confidentiality, if you participate in online programs, as with any activity on the internet, it is possible that your protected health information (PHI) may be exposed.
- You can choose at any point to return to standard care options that are recommended by your primary care clinical team.

Introduction

Please read this form carefully. This form tells you about a study called “Remotely Delivered Programs Targeting COVID-19 Stress-Related Depression and Substance Use.” This study is being conducted by Harvard Medical School researchers at Cambridge Health Alliance, in Cambridge, Massachusetts.

Taking part in this study is voluntary. You have the choice to take part or not. If you take part in the study, you may leave the study at any time for any reason. If you don’t want to take part, it does not change any part of the standard health care you may receive at Cambridge Health Alliance.

If you decide to take part in this study, you will be asked to sign this form. We will give you a copy of the signed form. Please keep your copy for your records. It has information, including important names and telephone numbers, for future reference.

This program aims to help you feel more supported and less isolated during this difficult time of COVID-19. It is not, however, guaranteed that you will experience these benefits.

The National Institutes of Health (NIH) is providing funding for this research. If you have any questions about the research or about this form, please ask us.

We will tell you about new findings that may cause you to change your mind about being in this study.

Purpose for the Study

The purpose of this research study is to learn if online groups, internet programs, and/or supportive calls at home help you learn to build resilience and mental wellness skills in the face of COVID-19 and its consequences. This study will examine how the different programs affect your well-being and your feelings of being supported, and the impact of this on your stress level, your symptoms of depression and anxiety, and substance use.

Approximately 200 participants will be in this study at Cambridge Health Alliance.

Reasons why you have been invited to be in this study

The reason why you have been invited to be part of this research study is because you are a patient at Cambridge Health Alliance. A CHA MindWell coordinator may have referred you to this study.

To take part in this study, you have to meet the following criteria:

- You are between 18 and 70 years of age.
- You‘ve been feeling stressed, sad, guilty, ashamed, numb, low motivation, anxious, or depressed.
- You are a current patient of CHA primary care or behavioral health
- You understand English well enough to understand procedures and questionnaires and provide informed consent.
- You have access to the internet and an electronic device with adequate data capacity to complete questionnaires and potentially attend study online videoconference groups.
- You are able to fill out surveys on a computer or an electronic device at home.
- You can be available on the appropriate evenings for the next 10-12 weeks if randomized to attend an online group during that time.
- You are NOT participating in another research study.

Period of Participation (how long you will be in this study)

If you choose to participate in this research study, you will first be screened to determine whether you are eligible for this study. You will be compensated for this screening even if you are not eligible to join the study.

If you are found to be eligible for the study, you will be randomly placed in one of three programs designed to help you feel supported during COVID-19. These three programs are online groups, internet programs, and/or supportive calls at home. These groups or supportive calls will take place for 8 weeks. You will be able to continue as part of the study for up to 24 weeks.

You will be expected to complete a survey session before your first online group, internet program, or supportive call at home, and again at 4, 8, 12 and 24 weeks. These survey sessions may last up to 60 minutes and you will be paid for time completing study tasks. You will also be expected to complete online computerized interviews every 4 weeks for the entire 24 weeks of the study. These monthly surveys may last about 10-15 minutes each.

We will ask you NOT to participate if you expect to be hospitalized in the next 24 weeks for a health problem. We will ask you NOT to participate if you expect to go to jail in the next 24 weeks. You may participate in this study if you are pregnant. No other experimental treatments or participation in other investigational trials are allowed during the study.

Procedures (what will happen during this study)

This study has 7 required (R) and 2 optional (O) components: consent/screening session (R), weekly surveys (R), longer surveys (R), follow-up surveys (R), an online group/internet program/supportive calls at home (depending on which program you are randomly assigned to participate in) (R), toxicology testing (R), study completion visit (R), daily diaries (O), and saliva collection (O). The optional sub-study components (daily diaries and saliva collection) will only be running during part of the study period, so only a sub-set of participants who sign-up during the time it is running will be eligible.

1. Consent/Initial Screening Session: You will sign this informed consent form if you are interested and eligible to participate in the study. A Research Coordinator will review the inclusion and exclusion criteria for the study with you to determine if you are eligible to participate in the study. This will include accessing the most recent CAT-MH assessment you have completed as a part of the CHA MindWell program and may also include a review of your CHA electronic health record.
2. Weekly Surveys: You will complete weekly computerized interviews on a website. These weekly surveys should take about 3-5 minutes for the first 8 weeks, and at baseline and once a month they will be a bit longer and take 10-15 minutes.
3. Longer Surveys: Before you start the online group, internet program, or supportive calls at home, you will be asked to complete a larger set of surveys that will take about 60 minutes to complete. You will repeat these surveys at weeks 4, 8,12 and 24.
4. Follow-up Surveys: You will complete follow-up surveys at Weeks 16 and 20 that will take about 45 minutes to complete.
5. Online Group/Internet Program/Supportive Calls at Home: As a part of the 24-week research study, you will be randomly assigned to participate in 8 weeks of either an online group, internet program, or supportive calls at home. These programs are designed to help you feel supported during COVID-19. The information from these groups and data from internet programs will be collected by the study team. If you are randomized to use an internet-based program, then the data you provide may be stored on the program's website and securely transferred to the CHA study team.
6. Testing for Alcohol and Drugs: All participants will provide oral fluid to test for alcohol and drugs at the beginning of the study (before being randomly assigned to one of three programs) and again at 24 weeks. These oral fluid tests for alcohol and drugs will be conducted via videochat with a study team member. Both you and the study team member will see the results of the alcohol and drug screening in real time. This oral fluid test is not FDA cleared, and should not be used on its own to make any decisions about your care. The results will only be used for research purposes.

7. Study Completion Visit: All participants will be asked to meet by videoconference with the study coordinator at week 24 to conduct an interview about substance use.
8. Daily Diaries (optional): After you sign the informed consent form, if you are determined to be eligible to participate in the study, you may be invited to complete 5 (out of 7) days of daily diaries about your feelings and daily experiences. You may also be invited to complete 5 (out of 7) days of daily diaries again on week 9 after completing the 8 weeks of either an online group, internet program, or supportive calls at home
   Saliva Collection (optional): You may be invited to participate in an optional study in which you will come to the CMC for a research coordinator to collect a saliva sample at the screening session and again between weeks 9-12 of the study to test for COVID-19 antibodies and IL-6 cytokines. The COVID-19 and IL-6 cytokine saliva collection results will not be shared with you.

Collection of identifiable private information or identifiable biospecimens:

We will collect data from your electronic medical records regarding visits with clinicians and referrals to psychiatric or substance use treatment. This will be from the year before this study and up to 1 year after you start the study. We look at your prescribed medications and health information. This information includes contact information, medication names and dosages, height, weight, your health-related behaviors, your mood, and the visits that you made to the hospital and to your primary care provider. You can choose to leave the study and remove our access to your data at any time. The study team will have access to your data up until the date of your withdrawal from the study.

If you participate in the saliva collection, the saliva specimens will be stored with a coded number and set of letters so that the specimen will not be readily identifiable by anyone. The specimens will be sent to a laboratory, but some part of the specimen may be stored in a research freezer indefinitely. Your identifiers will be removed from the identifiable private information or identifiable biospecimens. After such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

Support Calls and Text Messages:

You may be called by a member of the study staff at various times during the 24-week study. This will be a short (5-10 minute) outreach call to provide you support as you participate in the study. During this call, the study staff can help you answer any questions, help you with any problems you may have in filling out the surveys, provide support and hear about anything that you would like to share with the study staff. The research coordinator can call a behavioral health provider or help you to set up a televisit appointment with a behavioral health provider if needed. If you don't answer this phone call, the study staff will leave a message. A study team member may continue to call and leave several voicemails or reach out by email if they do not hear back from you. A study team member may also reach out to you via text message to remind you about various study assessments you might have forgotten.

Possible Risks, Discomforts, Side Effects, and Inconveniences

The following are possible risks and side effects associated with your participation in this study:

- Some questions that you will be asked are personal. You might feel stressed or embarrassed. You may ask to see the questions before you participate in the study. If you get upset or stressed, you can call the research staff. The research coordinator can call a behavioral health provider if needed.
- You may spend extra time learning techniques and doing study tasks.
- You might not benefit from this program.
- Despite strong efforts to maintain your confidentiality, your protected health information (PHI) might be exposed. All digital information collection and transfer using the internet carries the risk of loss of confidentiality due to privacy breach.
- You might experience eye strain from performing computer tasks.
- If you are randomly assigned to participate in a group:

  - You may have physical discomfort from any gentle movement that you do in your group.
  - You may feel anxious being in a group or due to what you learn or do in group.
  - Group members will be asked to keep what you share confidential, but they may not. You may be invited to share your experiences, but you will not be forced to share personal information in group and can always ask to speak privately with group leader afterwards if there is something you feel you really want to discuss but felt too worried to do so in group.
- If you are asked to participate in the optional saliva sub-study and are eligible, you may become aware of issues with your oral health or oral disease that you did not previously know about

We will be happy to answer any questions you have about these risks and/or side effects. Please talk with a study team member if you have any study-related questions or concerns.

Alternatives to Participation

Participation is **voluntary.** Whether or not you enroll in this study will not affect your health care at Cambridge Health Alliance. You may choose not to participate in the study and return to standard care options that are approved by your primary care or behavioral health clinical treatment team.

Benefits (good that may come from being in this research)

- You may learn about others who have similar problems as you do, helping you feel less alone.
- You may feel increased awareness of how your decisions impact your mental well-being by engaging in monthly computerized interviews
- You may learn skills for controlling behavior and improved well-being.
- You may feel less depression, anxiety, stress, and pain.
- You may feel more joy and gratitude.
- You may receive access to the proper level of wellness education, support or mental health care.

Some of these benefits may not help you directly. However, what we learn from this research may help others in the future. There is no guarantee you will benefit from being in the study.

Costs

You will not have any additional costs from being in this study. All study-related visits and procedures will be given to you at no cost. If you are referred to tele-visits with a behavioral health care provider, costs related to your standard care will be billed as usual to you or your insurance if you choose to have the visit.

Payment

You will be paid up to $160 (or $240 if you are eligible and enroll in an optional extra daily diary sub-study and a saliva collection sub-study):

- $20 for Screening/Consent visit
- $20 for Baseline Assessments
- $60 after 12 Week Assessment (includes weeks 4, 8, 12 assessments)
- $40 for 24 Week Assessment (includes weeks 16, 20, and 24 assessments)
- $20 study completion bonus (for >75% completion of study assessments)
- For participants enrolled in the optional extra saliva sub-study:
  - $40 for collection of 2 saliva samples ($20 per sample)
- For participants enrolled in the optional extra daily diaries sub-study:
  - $20 for completion of all baseline daily diaries
  - $20 for completion of all weeks 9-12 daily diaries

You will only be paid for each visit that you complete. You will be given your payment at the end of each visit. If you complete every visit in this study, then you will be paid a total of $160 for your time and effort ($240 if you enroll in the optional saliva sub-study (additional $40) and optional daily diaries sub-study (additional $40)).

Payment comes in the form of a gift card which can be redeemed throughout the study. We will send a new gift card via email at each payment timepoint after the corresponding visits. Your email address will be shared with Tango Card in order to send you these gift cards.

You will receive gift cards that will be sent as the study progresses. Study staff will email the gift cards with the amount of your study payment after your screening/consent, baseline, week 12, and week 24 visits.

Study-Related Injury

If you get hurt or get sick as a direct result of being in this study, emergency treatment will be given to you. All needed emergency care is available to you, just as it is to the general public. Any needed medical care is available to you at the usual cost. If you have depression or mental health symptoms that worsen during the study, you will be referred to an appropriate level of mental health care at CHA. You or your insurance carrier will have to pay for any such medical care.

Cambridge Health Alliance has not set aside any money to pay for a research-related injury or illness. There are no plans to pay for your treatment if you get hurt or sick as part of this study.

Voluntary Participation

Taking part in this study is voluntary. If you do not take part, you will not be punished or lose benefits that you have the right to receive. The quality of your medical care will be the same at Cambridge Health Alliance whether you take part in the study, refuse to take part, or decide to leave the study.

If you choose to take part and then decide to stop, tell a member of the research team. It may not be safe for you to suddenly stop being in this study. The study team will help you stop safely.

If you no longer want to participate in the assigned treatment group (“Group Discontinuation”), you may return to standard care options that are approved by your primary care or behavioral health clinical treatment team. You can leave the program to which you were randomly assigned, but still remain in the study and complete study activities and be paid for your time, including for survey sessions.

If you choose to withdraw from the study completely (“Study Withdrawal”), you will no longer be expected to complete study activities listed above and you most likely will not be able to continue in the program. Any information collected from you before the date you leave the study will be used in the research study. If you wish to withdraw from the study, please notify the study staff either in writing or via email that you wish to do so.

The research team may decide that you can no longer be in the treatment group (“Group Discontinuation”). This could be for several reasons, including:

1. You have had a bad reaction to the study.
2. Your mental health symptoms worsen substantially requiring referral to a higher level of care.
3. If you were randomly assigned to a group and did not follow all the group rules.
    a. You breached the confidentiality of other people in the group by sharing their information outside of the group.
    b. You threatened others in the group or provided serious disruption to group.

The research team may decide that you can no longer be in the study (“Study Withdrawal”). This could be for several reasons, including:

1. You threaten treatment staff or study staff.
2. You are unable to complete baseline survey sessions or lose access to the internet and you are unable to participate in the programs offered on the internet.
3. You meet study exclusion criteria.
    a. You are experiencing acute psychosis, mania, suicidality, self-injurious behavior, severe depression, or severe PTSD.
    b. You are judged to be cognitively unable to complete study surveys as determined by inability to complete this form, and by the cognitive screening process.
    c. You are currently participating in another experimental research study.
    d. You have previously participated in a related study.
    e. You expect to be medically hospitalized in the next 24 weeks.
    f. You expect to be incarcerated in the next 24 weeks.
    g. You are unable to participate in a group intervention without disrupting the group.

Daily Diaries Sub-Study

You may be selected to participate in a sub-study providing daily diaries for 14 days for measuring the effects of stress.

I agree to participate in the daily diaries.

☐ I agree ☐ I do not agree ☐ The diary sub-study is not available.

Salivary Collection Sub-Study

You may be selected to participate in a sub-study providing saliva for COVID-19 testing and for measuring the effects of stress.

I agree to participate in the saliva collection.

☐ I agree ☐ I do not agree ☐ The saliva sub-study is not available.

Audio-Video Recording of Group Sessions

You may be selected to participate in some group sessions during the course, which may be audio-video recorded. This is so that we can monitor the way the group leader leads each session. Audio-video will NOT be linked to any personal or identifying information collected in other aspects of the study, including your name. Please indicate your agreement to be audio-video recorded during group sessions.

I agree to be audio-video recorded during group sessions.

☐ I agree ☐ I do not agree

Future Contact

Sometimes the study team has information about other studies or opportunities that might interest you. Please indicate below whether you give permission for us to contact you about future studies or opportunities via email or phone. We will retain your phone number and e-mail address in a separate database from the study database.

I agree to be contacted in the future about other studies or opportunities.

☐ I agree ☐ I do not agree

Text and Email Contact

The study team will ask you to provide your email, and text number. This is so that we can reach you regarding study surveys. We will use email and text to contact you about study assessments related to the group intervention, should you miss a study assessment.

I agree to be contacted via text and email.

☐ I agree ☐ I do not agree

Privacy / Confidentiality

There are laws (state and national) that protect your health information to keep it private. We follow those laws. Your identity, medical records, and study data will be kept confidential, except as required by law. We will protect all of your health information, including your Protected Health Information or "PHI." Your PHI is your individually identifiable health information. This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local proceeding. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the agency which is funding this project.

If you take part in this study, you agree to let the research team use your medical information. Do not take part in this study if you do not want the research team to access your health information.

We will follow these guides:

- The research team will view your health information from the year before you enrolled in the study. during the life of this study, and for three years after you finish the study.
- We will not include any information that could identify you in any publication.
- Anonymous data from this study may be made available on a public database – it will never be made available in a way that can identify you.
- We will remove all of your identifiable information (name, address, telephone number, *etc*.) from the study database 7 years after the study has been completed.

We will make every effort to keep your information private, but we cannot guarantee it. The Cambridge Health Alliance Institutional Review Board (IRB) is responsible for protecting the safety and welfare of people who take part in research studies at our hospital. IRB staff may ask to look at any research records to make sure the study team is following the laws and rules to protect you. Certain government agencies, including the Office for Human Research Protections and the U.S. Food and Drug Administration (regulates drug and device studies), may also look at records that identify you. Additionally, the study staff may be required to disclose confidential information if it becomes clear that you risk harming yourself or others.
Sometimes, we are required to share your study records with others, too, including:

- Other researchers conducting this study,
- The study sponsor and any companies that the sponsor uses to oversee, manage, or conduct the study,
- Research collaborators,
- Data and Safety Monitoring Board (this is an independent group of experts who monitor study participant data and safety while a study is taking place),
- Clinical staff not involved in the study, but involved in your regular treatment,
- Insurance companies.

If any of these groups ask to look at your information, then we cannot prevent it from being shared. Once information is shared, we cannot guarantee any further confidentiality and privacy. If you are randomized to use an internet-based program, then the data you provide may be stored on the program's website. This kind of data may include your number of logins, progress on the site, and assessments of mental health symptoms.

- **Despite our best efforts to protect privacy and ensure confidentiality, data breaches can happen when you are using internet-based technology.**

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this web site at any time.

Period of Authorization

Your authorization on this research project will expire 10 years after completion of data gathering for the study. If you change your mind and want to withdraw your authorization please tell a member of the study team or write to the HIPAA Privacy Officer for Research, Cambridge Health Alliance, 1493 Cambridge Street, Cambridge, MA 02139. If you withdraw your authorization, you may no longer be allowed to participate in the study described in this form.

Getting Help (Contacts)

If you have questions about this study, please ask a member of the study team. Some questions people have:

- What are the risks and benefits of being in this study?
- What other choices are available?
- What are my rights as a research participant?
- What should I do if I feel pressured to take part in this study?
- How is my health information used in this study?
- How will my health information be protected?

Call or email the study investigators for answers to any study-related questions or if you get hurt or sick as a result of being in this study. This is how to contact us Monday to Friday during regular business hours:

The easiest way to reach the study team with questions is by email at resiliencestudy@challiance.org.

You can also call study investigators if you have an urgent question or concern.

Zev Schuman-Olivier, MD (Principal Investigator)	617-591-6056
Carl Fulwiler, MD, PhD (Co-Principal Investigator)	617-575-5728
Gabriella Conversano (Research Coordinator)	857-270-0666
Kayley Okst (Research Coordinator)	857-270-0372

On nights and weekends, you may contact your healthcare provider if any urgent issues arise.

If you have questions about your rights as a study participant, please contact either the IRB office or the Patient Relations Department. The offices are open Monday to Friday (not holidays) from 8:30am-5:00pm:

IRB Chair: Dr. Lior Givon
Telephone: 617-806-8702

Patient Relations Manager: Lorraine Vendetti
Telephone: 617-665-1398

Confirmation from Person Obtaining and Documenting Consent

I, the study participant, have read this form or it has been read to me. I understand my part in this study and have had my questions answered to my satisfaction. I agree to take part in this research study.

_____ _____
Participant's Signature Date

I have informed the study participant, _____ of:
Participant's Printed Name

- The procedures, purpose, and risks related to participation in the above-described study;
- How his/her health information may be used, shared, and reported, and;
- His/her privacy rights.

The study participant has been provided with a signed copy of this form.

_____ _____
Signature of Researcher Obtaining Consent Date

_____
Printed Name of Researcher Obtaining Consent