Multilevel, Multidisciplinary, Faith-Based Participatory Interventions to Reduce COVID-19 Related-Risks among Underserved African Americans

NCT04542343

04/23/2021

Charles R. Drew University of Medicine and Science
CONSENT TO PARTICIPATE IN A RESEARCH STUDY
Version 1.1, April 5, 2021

Title of the Study: **Multilevel, Multidisciplinary, Faith-Based Participatory Interventions to Reduce COVID-19 Related-Risks among underserved African Americans**

Principal Investigator: Mohsen Bazargan, PhD
Telephone Number: Tel: 323-357-3655

Key Information about this Research Study

Charles R Drew University of Medicine and Science and Dr. Mohsen Bazargan are being paid by the Accelerating Excellence in Translational Science (AXIS) program, the Community Engagement Core to conduct this study. We are planning to enroll 265 participants in this study and the study will last three months. Your participation in this study is voluntary. Please read the information below, and ask questions about anything you do not understand, before deciding whether to participate.

Why is this research study being done?

The purpose of this study is to see if we can help people with chronic health conditions to improve managing their condition during the COVID-19 pandemic. For example, by scheduling needed doctors' visits, taking their medication exactly as their doctor has prescribed, following a healthy diet, and engaging in moderate exercise.

What will I be asked to do and how long will I be in the study?

If you volunteer to participate in this study, we would ask you to do the following:

1. An African American Health Advisor (fellow parishioner) will assess your physical ability in terms of sight, hearing, and ability to read, which is necessary since these workshops and assessments will be conducted online, we will need to access, and you may need more support.

2. You will be asked to participate in pre intervention (made up of two parts) and post intervention (made of one part) surveys lasting about 70 and 45 minutes, respectively.

3. You will need to participate in six bi-weekly (occurring every two weeks) workshops that will provide specific information on reducing risk for COVID-19.

4. You will need to participate in individualized online visits with an African American health advisor to discuss management of chronic conditions, in addition to receiving timely health assessment, coaching, and education.

What are some reasons why I might want to take part in this study?

You may not directly benefit from participating in this study. You should not expect your condition to improve as a result of participating in this research. However, based on experience with this type of studies researchers believe it may be of benefit to you with your chronic health condition. You have the right to refuse to participate in this study.

What are some reasons why I might <u>not</u> want to take part in this study?

- There is a risk that some of the conversations during the survey may make you feel uncomfortable, embarrassed or stressed (psychological risk). But this risk is minimal. You can participate in the survey/visits as much or as little as you like. You can stop the survey/visit whenever you feel uncomfortable. You can stop answering any question that makes you feel uncomfortable. You can also stop your participation in the study at any time. In any case, our trained study staff will answer any study related question that you may have, before starting your participation, or during your participation.
- Our study does not include any invasive procedures and thus the risk of physical harm is minimal and very low.

Do I have to take part in the study?

Taking part in research study is voluntary. You do not have to take part and you can stop at any time.

What if I have questions or concerns?

Please contact Mohsen Bazargan PhD , Department of Research at 323-357-3655, who is in charge of this study. Additional contact information can be found on the last page of this informed consent.

Additional Information about this Research Study

The researchers will tell you about this study. It is your decision to take part or not take part in the research. Before you decide to volunteer for this study, you should

1. ask questions you do not understand;
2. learn as much as you can about the study; and
3. talk it over with your family, friends, and doctor.

WHY AM I BEING ASKED TO TAKE PART IN THE STUDY?

- African American
- 65 years of age or older (must have California ID or California Driver's license to verify age)
- 55 years of age or older must have a Chronic Health condition (must have California ID or California Driver's license to verify age)
- Able to speak and understand English
- Relatively healthy and functioning
- Able to read
- Able to hear

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

Your other choices may include:

- Taking part in another research study.
- Not take part in this research study.

WILL I BE PAID?

You will be paid $25 for each of the 2 part pre-intervention survey and $ 25 for the post-intervention survey; totaling a possible $75 payment for completion of all three parts.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

Neither you nor your insurance company will be billed for your participation in this research.

WHAT IF I BECOME SICK OR INJURED BECAUSE OF TAKING PART IN THIS STUDY?

In the event of a research related injury or if you experience an adverse reaction, please immediately contact:

Principal Investigator	Mohsen Bazargan, PhD	Charles R. Drew University of Medicine and Science, 1748 E. 118th Street, Life Science Building, Los Angeles, CA 90059 Tel: 323-357-3655

- **PRIVACY AND CONFIDENTIALITY**

No information about you, or provided by you during the research will be disclosed to others without your written permission, except:

- if necessary to protect your rights or welfare (for example, if you are injured and need emergency care); or
- if required by law (i.e., child abuse, elder abuse).

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

National Institutes of Health (NIH), who funds this research, may need to review records of individual subjects. As a result, they may see your name; but they are bound by rules of confidentiality not to reveal your identity to others.

CAN I STOP BEING IN THE STUDY?

Your participation in this research is VOLUNTARY. If you choose not to take part in the research study, that will not affect your relationship with Charles R. Drew University of Medicine and Science, or your right to health care or other services to which you are otherwise entitled. If you decide to take part in the study, you are free to withdraw your consent and stop at any time without affecting your future care at above-mentioned place.
If you are a CDU student, you may choose not to take part or drop out of the study at any time. This will not affect your grades or class standing at CDU. You will not be offered or receive any special consideration if you take part in this research.

If you are a CDU employee, your participation in this research is in no way part of your university duties, and your refusal to take part will not in any way affect your employment with the university, or the benefits, privileges, or opportunities associated with your employment. You will not be offered or received any special consideration if you take part in research.

CONSEQUENCES OF WITHDRAWAL

If you decided to withdraw from the study, there are no consequences if you do not complete the study.

CAN THE RESEARCHERS REMOVE ME FROM THE STUDY?

The investigator may stop you from being in the research even if you would like to continue:

- If you are found not eligible at the time of your first survey
- If you are extremely uncomfortable and/or if it is not safe for you
- If you are under the influence of drugs or alcohol at the time of interviews

The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

If you must stop being in the study because the research team asks you to (not because you have decided on your own to stop), the study will be done with the parts of research that you have completed.

NEW FINDINGS

During the study, you will be told of any important new findings (either good or bad) that might cause you to change your mind about staying in the study. If new information is given to you, your consent to continue participating in this study will be re-obtained.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

In the event of a research related injury or if you experience an adverse reaction, please immediately contact one of the researchers listed below. If you have any questions about the research, please feel free to contact

Principal Investigator	Mohsen Bazargan, PhD	Charles R. Drew University of Medicine and Science, 1748 E. 118th Street, Life Science Building, Los Angeles, CA 90059 Tel: 323-357-3655

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

You may withdraw your consent at any time and end your participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research participant, please contact,

Charles R. Drew University of Medicine and Science
Institutional Review Board/Office of Research Integrity and Compliance
1731 East 120th Street, Los Angeles, CA 90059
Telephone: 323-563-5902
FAX: 323-563-4826
e-mail: irb@cdrewu.edu

SIGNATURE OF RESEARCH PARTICIPANT OR LEGALLY AUTHORIZED REPRESENTATIVE

en
given a chance to ask questions and all of my questions have been answered to my satisfaction. I am not giving up any of my legal rights by signing this consent form. I have received a copy of this consent form, which will show all signatures and dates. In addition, a copy of the Participant's Bill of Rights will be given to me, if applicable.

BY SIGNING THIS FORM, I AGREE TO TAKE PART IN THE RESEARCH DESCRIBED IN THIS CONSENT FORM.

Name of Participant

Name of Legally Authorized Representative (if applicable)

_____ _____
Signature of Participant or Legally Authorized Representative Date

SIGNATURE OF INDIVIDUAL OBTAINING CONSENT

I have explained the research to the participant or his/her legally authorized representative and answered all of his/her questions to the best of my knowledge.

Name of Individual Obtaining Consent Role in the Study (e.g. PI, coordinator)

_____ _____
Signature of Individual Obtaining Consent Date (must be the same date as the participant)

SIGNATURE OF WITNESS (IF REQUIRED BY THE IRB)

My signature as witness certifies that the participant or his/her legally authorized representative signed this consent form in my presence as his/her voluntary act and deed.

_____
Name of Witness

Signature of Witness Date (must be the same date as the participant)

Important Contact Numbers for the Research Study

Questions about the Research Study

Principal Investigator:

Mohsen Bazargan, PhD.

Questions about Possible Research-related Injury

Principal Investigator: Mohsen Bazargan – office # (323) 357-3655

Co-Investigator: Hector Balcazar – office # (323) 563-5841

Study Coordinator: Humberto Sanchez – Office # (323) 249-5715

Emergency: Call 911

Questions about Your Rights as a Research Participant

Charles R. Drew University of Medicine and Science
Institutional Review Board
Office of Research Integrity and Compliance
1731 East 120th Street
Los Angeles, CA 90059
Tel: 323-563-5902
FAX: 323-563-4826
E-mail: irb@cdrewu.edu