HSPC-2019-0978
Approved 4/4/23

Still Climbin' Project

Consent to Act as a Research Participant

You are being asked to participate in *Still Climbin'*, a research study. Your participation is voluntary. If you join the study you can change your mind and quit the study at any time. If you decide to quit the study it will not affect any services you receive at APLA Health. If you tell us that you do not want to be in the study, we will not make any more attempts to contact you. You should feel free to ask questions and should understand the study completely before you agree to participate.

Who is doing the study?

APLA Health and RAND Corporation are doing the study. The National Institutes of Health is paying for the study.

What is the purpose of the study?

The purpose of this study is to test a program designed to support Black/African American men who have had sex with other men in dealing with stress and discrimination in their lives, and in getting preventive health care. We are recruiting about 300 Black/African American men who have had sex with men.

Who can participate in the study?

You are eligible if you meet the following criteria:

- 18 years of age or older
- Assigned male at birth
- Self-identify as a Black/African American man
- Report having sex with men in the past 24 months

What will you be asked to do?

If you are eligible and decide to participate, you would do the following:

Group program: You may be asked to participate in an 8-week program that consists of group sessions that discuss coping with discrimination due to your race and sexual orientation, and how discrimination affects your health and use of health care. Sessions may be offered in-person in the Los Angeles area or virtually (e.g., via Zoom or a similar online platform). The in-person group will meet once per week for approximately 2.5-3 hours per week. The virtual sessions may be split in two and offered on two separate days each week, so you would attend two shorter sessions in one week. Halfway through and at the end of the program session participants will be asked to fill out a brief survey on what they thought about the session. The sessions will be audio-recorded so that we can monitor how well the facilitator is conducting the groups. We will randomly select who is enrolled in the program (similar to flipping a coin). If you are randomly selected to be enrolled in the program, you would start within the next two months, approximately. If you are not selected to enroll in the program, we can provide lists of resources that are available in the community or at APLA Health.

Surveys: You will be asked will complete four 1-2 hour surveys at APLA Health or by phone or online over the next 12 months. You will complete a survey today, and again in about 4, 8, and 12 months from today. Ideally you will complete the survey in a private space. The survey asks questions about your background, your physical and mental health, your experiences with discrimination, the ways you deal with stress, your substance use, your sexual behaviors, and other topics. You will read the survey and can listen to the questions on the computer, or you can ask the interviewer to read them to you. If the survey is done by phone, an interviewer will read the questions to you.

Check-in visits with study staff: In addition to the surveys, we will check in with you three times during the study, in about 2, 6, and 10 months from today to make sure your contact information is current and ask about any health care services you have received.

Health care information: We will ask your permission to obtain from your medical provider information on preventive health care visits. For this, you will sign an additional consent form called a "HIPAA Authorization to Release Confidential Information" form. If you choose not to fill out this form, you will still be allowed to enroll in the study.

Staying in contact: To ensure we are able to maintain contact with you, we will ask you to give us contact information of people who could help us reach you. We will only contact them if we cannot find you. You can give as much or as little information as you feel comfortable sharing. We will not tell them your personal information. If you give us permission we will only say that we are trying to contact you about a health study. If we cannot reach you through these methods we may also search public records, such as public databases.

You can choose whether to finish surveys and group sessions or not. You can leave a visit at any time without anything bad happening, and can skip questions you don't want to answer and still be in the study.

If you are not assigned to do the group program, you will still be asked to complete the surveys and check-in visits, and provide healthcare information and contact information.

Are there risks in participation?

You may feel embarrassed or uncomfortable at being asked to discuss sensitive topics, including about discrimination, sexuality, and your health and healthcare. Remember that your participation is entirely voluntary. You are free to refuse to answer any question and you can choose to end your participation in the study at any time.

There is a possibility that, if you participate in the group sessions, you might encounter someone you already know in the group, and you may experience discomfort as a result. In addition, it is possible that other group members could share information about you or others in the group with people from outside of the group. To reduce the risk of this occurring, study staff will remind the group about the importance of confidentiality at the beginning of each group session. We will ask that only first names are used in the group as another way to protect confidentiality.

We may contact you via text message, telephone, or email to remind you of your appointments. If you choose to receive appointment reminders on your phone, you are advised not to share it with others and to delete messages you don't want others to see. In addition, you may be charged for text messages depending on your cell phone plan. To minimize the risk of appointment reminders being seen or heard by others, a member of the research team can show you how to password lock your mobile phone and how to erase text and voice messages and emails from your phone, if you wish.

What are the potential benefits of participating?

You may find it helpful to talk about your health and healthcare, or learn about ways to better cope with stress and discrimination. You may also feel good about yourself for helping researchers to develop programs for Black/African American men that, if successful, could be used in community organizations around the country.

How will the study protect confidentiality?

All of the information that you provide to us will be kept private and confidential, and only designated study staff will have access to all of the information you provide to us, including personal information that would identify you.

We will store your survey responses, the information you provided when you were screened, information we obtain from your medical records, and information you might provide during a group session separately from documents that have your name on them (like this consent form). Any information you give us will be connected to a unique ID number instead of your name. All hard copy study documents will be stored in a locked file cabinet used by the study staff only. We will keep digital study files and audio-recordings of the group sessions in a password-protected folder on a secure server. After the study, all information that could identify you, such as your name and contact information, will be destroyed.

A Certificate of Confidentiality from the National Institutes of Health protects your research data further. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily without your consent, information that would identify you as a participant in the research project under the following circumstances: if we think you are at immediate risk of seriously harming yourself or others we may be legally obligated to notify others, such as calling 911 emergency services. In addition, if we learn about current child abuse or elder abuse, we may discuss it with you and seek help from authorities to protect you or another person. In such cases, we would first ask you to speak with a study supervisor who would assess the situation and offer referrals.

De-identified survey data from this study may be shared with other researchers. De-identified information means that all personal information about participants such as name, address, and phone number is removed and replaced with a code number that cannot be used to identify you. Other researchers can then file an application with this study's Principal Investigator, Dr. Laura Bogart, to obtain access to your de-identified study data for research purposes. The Principal Investigator and members of RAND's Human Subjects Protections Committee, who know how to protect health and science information, will look at every request carefully to minimize risks to your privacy. By sharing data, researchers hope to learn new and important things about engagement with preventive health care more quickly than before. If you do not want your data to be shared with other researchers, you may contact the Principal Investigator, Dr. Bogart.

What will you get for participating in the study?

You can receive up to $230 if you complete all of the study assessments:

- You will receive $50 for each of the 4 survey visits, including today (up to $200 total)
- You will receive $10 for each of the 3 check-in visits (up to $30 total)

If you are randomly assigned to participate in the in-person Still Climbin' program, you will also receive $20 for each group session that you attend (up to $160 total for 8 sessions attended). Participants in the

virtual group program will receive $20 for each of the split sessions that you attend (up to $-280 total for 14 sessions attended). You must attend at least half of each session to receive the gift card. Virtual group program participants will receive an additional $5 for mailing a signed HIPAA form to study staff.

What if I have questions about the study?

If you have questions about the study, or if you have concerns about the study after you enroll, please contact the study investigators:

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3741 S. La Brea Ave.
Los Angeles, CA 90016
(213) 201-1522

Laura M. Bogart, Ph.D.
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You may withdraw your consent at any time and discontinue 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 about your rights as a research participant or need to report a research-related injury or concern, you can contact **RAND's Human Subjects Protection Committee** toll-free at (866) 697-5620 or by emailing hspcinfo@rand.org. If possible, when you contact the Committee, please reference Study # 2019-0978.

Consent

Participant Statement:

My signature indicates that I have read (or had read to me) this consent form, that I understand the information it contains, and that I willingly agree to take part in this research study. I have been provided with a copy of this consent form.

Participant name (please print): _____

Signature: _____ Date:_____

Investigator or Representative Statement

I have fully explained to the participant the nature and purpose of the procedures described above, and the risks involved in its performance. I have answered all his questions to the best of my ability. I will inform the participant of any changes in the procedures or the risks and benefits if any should occur during or after the course of the study. I have given a copy of the consent form to the participant.

Signature: _____ Date:_____