Cover Page for ClinicalTrials.gov

Document: Informed Consent

Official Study Title: Racial inequities in end-of-life healthcare: how perceived discrimination affects communication and decision-making during serious illness

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PROMOTING RESOURCES IN STRESS MANAGEMENT (PRISM)

UNIVERSITY OF WASHINGTON
CONSENT FORM

Researchers: Crystal E. Brown, MD MA,
Assistant Professor
Division of Pulmonary, Critical Care, and Sleep Medicine
University of Washington
phone: 206-744-5018; email crysb@uw.edu

Abby Rosenberg, MD MS MA
Associate Professor
Department of Psychosocial Oncology and Palliative Care
Department of Pediatrics
Dana Farber Cancer Institute, Boston, MA

Arisa Rei Marshall
Research Coordinator
Division of Pulmonary and Critical Care Medicine
University of Washington
email: arisarei@uw.edu

Researchers' statement

We are asking you to be in a research study. This form is to help you decide whether to be in the study or not. Being in this study is voluntary. Please read this carefully. You may ask any questions about the study. Then you can decide whether or not you want to be in the study.

KEY INFORMATION ABOUT THIS STUDY

The purpose of this study is to understand how well a program designed to help people experiencing serious illness better manage the stress and distress associated with healthcare discrimination called Promoting Resources in Stress Management (PRISM) works, as well as if it is effective and acceptable.

You will be randomized to the PRISM program arm or usual care. Subjects in the PRISM program will participate in five one-on-one sessions over 3 months. Each session will focus on a specific topic and related skills or resources that can help subjects cope with the stress of their diagnosis.

All subjects will be asked to complete surveys at 1- and 3-months after the beginning of the study. You will receive a $30 gift card for each survey you complete.

Subjects randomized to the PRISM program that complete all sessions will also be asked to participate in an interview to provide feedback about the program.

The main risks associated with being in this study include feeling upset or stressed due to the topics discussed during the PRISM sessions or questions asked during the interview.

PURPOSE OF THE STUDY

What is the goal of this study?
The goal of this study is to find the best way to help patients manage the stress and distress of medical racism in the face of serious illness and be better able to "bounce back" or be resilient after a difficult situation. To do this, we have developed a study entitled "Promoting Resources in Stress Management" or "PRISM." PRISM is a program, meaning that it aims to change something, in this case, behavior and thinking in a way that will reduce the impact of stress in everyday life. This version of PRISM has been adapted from other versions that have worked well for young adults with cancer as well as their families. The original PRISM was designed with feedback from patients and families. This version of PRISM was created with feedback from patients similar to you. We are trying to make it better so that we can provide this program to more patients to help them better deal with the stress of experiencing medical racism.

Why do I have the option of joining the study?
You have the option to take part in this study because of your responses in the first survey that you completed. In that study, you stated that you have felt discriminated against or have experienced discrimination by healthcare workers.

How many people will take part in the study?
We think about 90 people will take in this study and half of them will participate in PRISM.

STUDY PROCEDURES – What You Will Be Asked to Do
You would be randomized into the study, meaning that you would be randomly selected to either participate in the PRISM sessions or not. Whether you receive PRISM or not, you will receive all the same care from your primary medical, social work, case manager, and other care teams. If you were randomly selected to participate in the PRISM program, it would include five sessions with a trained researcher. These sessions will be about 10-30 minutes each. The sessions can be done while you are here in the hospital or at home by phone, web-based app, or video call.

<u>There are five sessions in PRISM</u>:
1. Methods of stress management
2. Goal setting
3. Catching negative thoughts
4. Benefit finding
5. Coming together (Part 1) and Racial Healing (Part 2, **optional**)

<u>Racial healing</u>**:** The fifth session of PRISM is focused on racial healing and medical racism. This session is optional. After this session, you may or may not want to discuss concerns that you have about medical racism with your primary inpatient team. If you do decide to talk with your team about your concerns, you may either do so yourself or we can support you. With your permission, we can share your concerns with your team if you think it would be helpful. The information we share will not include identifiable information about specific providers, since we believe it's important to address these kinds of concerns as a team. You may decide if or how you would like to discuss these concerns with your team. You may wish to make the team aware, but not to talk

about these concerns with them. You may talk about them with the team yourself. If you would like, the PRISM coach can be present at this meeting with your care team. The length of the meeting depends on what you want to talk about, but most meetings last between 30 minutes to an hour. These meetings will be conducted as part of a related study entitled "Engaging Medical Providers in Discussions about Medical Racism."

If you are selected to participate in PRISM, we will offer you weekly "boosters" which include brief contacts over the phone for opportunities to practice specific skills.

We will audio record all of the sessions to make sure that the researchers leading the sessions are consistent in how they do it.

In addition, at the beginning of your sessions, we will ask you a few questions about how useful the PRISM experience has been for you so far. We would like to keep this. You may also give us worthwhile feedback regarding your impression of the sessions during the sessions and we would like to keep those thoughts as well. These portions of the audio recordings will be typed out and saved for future research purposes. These are the only portions of the audio recordings that will be saved. No identifying information (like your name) will stay connected to your data. Before each session, we will remind you that the session will be audio recorded before we start.

If you are randomized to PRISM, you will be invited to download the PRISM app, available in the iTunes and Google Play stores. It is free, but the content is only accessible with a password that is provided by the PRISM team. This app has content that allows you to practice skills between sessions. If you are interested in this content, but do not have a smartphone, we will provide worksheets that you can use.

Regardless of whether you participate in PRISM or not, you will be asked to complete a survey, much like the one the one you completed to enroll in this study one month and three months from now. It will take approximately 10 minutes to complete. You can complete this survey verbally, over the phone, or by pen and paper.

We will be contacting you either by phone and/or email to remind you about the surveys ahead of time and to remind you to complete and return them back to us.

We will also review your electronic medical records to see what kind of care you receive within one year after your enrollment in this study. We want to know what types of treatments you are receiving and how you are doing with it.

If you are randomized to PRISM and after you complete all the sessions, we will ask you to participate in an interview to give your feedback about your thoughts about what PRISM was like and how we can improve it. If you participated in the racial healing session, we will also ask you if that session was helpful, if you had any conversations with your doctors about medical racism, and how they went. We will audio record this interview and keep it to help us make PRISM better. No identifying information such as your name will stay connected to the data.

We prefer that each session is completed individually but in case of preference or discretion, we may combine sessions, up to two sessions total, to be done at the same time.

How long will I be in the study?
If you choose to take part in all the study visits and surveys, you will be in the study for 3 months.

If you choose to join the study, you can **stop at any time for any reason.**

The research team could also decide to take you out of the study. This might happen if you cannot complete the study visits. If we ask you to leave the study, we will always explain why.

Would it cost me money to be in the study?
If you take part in this study, there will be no cost to you or your insurance company.

Will I be paid if I join this study?
As a sign of appreciation for participating in this study, we will give you a $30 gift card with the surveys that you fill out at 1-month and 3-months after enrollment, regardless of whether you are receiving PRISM or not, for a total of $60.

RISKS, STRESS, OR DISCOMFORT
There are potential harms or risks if you take part in this study. One risk is that the sessions talk about sensitive matters and asks you to identify stressors and negative thoughts, particularly those related to feeling discriminated against by healthcare workers while you are sick. The topics covered may make you feel sad, anxious, depressed, fearful, or doubtful. All of your answers will be kept strictly confidential except if there is concern of thoughts of self-harm or harm to others; if we see an immediate threat to you or another's safety, we will seek appropriate help to support you. No physical risks are expected to arise from the study.

You may feel stress or discomfort at being asked questions about your care and any disagreement or conflict you may have experienced while in the hospital. You may feel that participating in the study is an invasion of your privacy. You may also feel stress related to having your interview recorded and concerned about the possibility that your confidentiality could be breached. You may still participate in the study without having your interview recorded. If you do give permission to record the interview, you can change your mind, and the recording will be stopped and deleted. You may stop the interview at any time and you do not have to answer any questions that make you feel uncomfortable. If the interview causes you distress, you may let the study leader, Dr. Brown, know either in person or at the phone number above. You will be referred for additional support. Your consent for your participation is completely voluntary. We will take precautions to keep the information you provide and the information about your health secure and confidential.

Racial healing: You may be worried about the potential risk of retaliation from the doctors and nurses caring for you. For example, you may worry that they may change how they speak with you, or that your medical care will get worse. We think this is extremely unlikely. If there are any medical racism concerns about anyone caring for you, we will provide this feedback in a

deidentified way, meaning we will not name a specific individual. This is to provide everyone with an opportunity to learn how to better provide anti-racist care. Additionally, we know that when doctors and nurses are part of a research study, they are extremely unlikely to provide anything less than their best care.

In the extremely unlikely event that blatant and unlawful retaliation and discrimination does occur by any healthcare worker, the research team will employ the help of appropriate University of Washington/Harborview Medical Center personnel to report the behavior.

BENEFITS OF THE STUDY

Potential benefit to you: There may not be any direct benefit to you if you give permission for your participation in this study. There may be benefits, however, and that we think PRISM will lessen psychological distress and improve quality of life.

Potential benefit for others: There may be a benefit to others, and we hope that this study helps us better understand how to foster resilience and promote better quality of life in patients facing medical racism.

YOUR OPTIONS

You do not need to participate in this study. This is completely voluntary. You may choose to be a part of this study or you may decline. If you decline your care will not be affected in anyway.

You are free to request a conversation with your providers at any time and do not have to participate in the fifth PRISM session in order to do so.

Feel free to ask the research team any questions that you have about participating in this study.

SOURCE OF FUNDING

The study team and/or the University of Washington is receiving financial support from the National Institute on Minority Health and Health Disparities for this study.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. 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.

RESEARCH-RELATED INJURY

If you think you have been harmed from being in this research, contact the study leader Dr. Crystal Brown at 206-744-5018 or crysb@uw.edu.

CONFIDENTIALITY OF RESEARCH INFORMATION

All of the information you provide and that we collect will be confidential. This means that there will be a link between the information (data) we collect and your identifying information. This link will be in the form of a specific identification code that we will make up for this study. The information that identifies you and the data we collect will be stored in separate protected files.

The audio recording that is made during your interview will be kept indefinitely. Your identifying information, such as names and titles, will be removed from the audio recordings. The recording of the interview will be transcribed (written out) without any identifying information included. The audio recording and the transcript will be kept securely in the study offices at the University of Washington.

All of the information you provide will be confidential. We will not share your interview answers with your doctors, nurses, or anyone caring for you. Participating in the study will not affect your current or future medical care. However, if we learn that you intend to harm yourself or others, we must report that to the authorities.

You may choose to have a one-on-one or group conversations with providers on your care team about your experiences of medical racism. If you choose to speak with your care team in a group setting, the confidentiality of the conversation cannot be guaranteed. Therefore, we ask that identifying details of the conversation are not shared outside the group in order to maintain privacy.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your study records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

We have a Certificate of Confidentiality from the U.S. federal National Institutes of Health which allows us to keep your identifiable research information confidential from legal proceedings or in response to a legal request unless you give us permission to release it. You or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection, including mandatory reporting, institutional monitoring, and others as listed elsewhere in this consent form.

The Certificate expires when the NIH funding for this study ends. Currently this is 6/30/2025. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

USING YOUR DATA IN FUTURE RESEARCH

The information we obtain from you for this study might be used for future studies. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you. We will remove anything that might identify you from the information. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. If you wish to withdraw, please contact the researcher listed on page 1 of this consent form.

There is a box you can check if you give us permission to audio record your interview. Checking the "YES" box means that we have permission to record you during the interview.

Printed name of study staff obtaining consent | Signature | Date

Participant's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I will receive a copy of this consent form.

YES □ I am willing to be audio recorded during the PRISM sessions and during the post-PRISM interview.

NO □ I am NOT willing to be audio recorded the PRISM sessions and during the post PRISM interview but would still like to participate in the study.

Printed name of participant | Signature of participant | Date

Copies to: Researcher
Participant