Information Visualization to Improve Pain Communication Between Providers, Interpreters, and Patients with Limited English Proficiency

NCT04975789

12/10/2021

University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research

Study Title for Participants: Visualization to Improve Pain Communication

Formal Study Title: Information Visualization to Improve Pain Communication Between Providers, Interpreters, and Patients with Limited English Proficiency

Lead Researcher: Dr. Maichou Lor, PhD, RN (Phone: (608) 265-4248; Email: mlor2@wisc.edu)

Where Lead Researcher works: School of Nursing

Invitation

We invite you to take part in a research study about pain communication. We are inviting you because you self-identify as Hmong, can speak and understand Hmong, are older than 18 years old, and self-report pain at the time of recruitment.

Why are researchers doing this study?

The purpose of this research study is to determine if a pain assessment tool can help non-English speaking Hmong patients better communicate their pain with healthcare providers in a primary care setting. We are doing this research because Hmong patients, interpreters, and healthcare providers have shared that it is challenging for Hmong patients to describe their pain including location and quality of pain.

This study is being done at the University of Wisconsin (UW)- Health Family Medicine Clinics in Madison, WI. A total of about 40 people will participate in this study. These 40 people will take part in the study here at the UW-Madison.

Funding for this study is provided by the National Institute of Health.

What will happen in this study?

If you decide to participate in this research study, the researchers will ask you to:

1) Allow a study team member to observe your interactions with your doctor provider and the medical interpreter

2) Allow us to record your conversation with the provider and interpreter during the clinic visit. The audio recordings are being collected to help us better understand the pain information discussed.
3) Complete a form with images and use it with your interpreter and provider to communicate your pain
4) Complete three short surveys on your understanding of provider, satisfaction with communication, and answering questions about yourself and about how we can improve the use of the pain images
5) Answer some questions about your pain after four weeks of your clinical visit

You may skip any question on the survey and interview that you do not wish to answer. If you complete all study activities, you will be in the study for four weeks.

Please note, we will first observe 20 visits before we use the form with images. Then we will observe 20 visits using the form with the images. You can participate in either part of the project.

Protected health information (PHI) used in this study

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify. To do this study, we will use the following kinds of PHI:

- Name
- Telephone
- Things you tell the researchers about your health
- Information about your pain, which we will from your health care providers such as UW Health.

Do I have to be in the study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study to get care for your pain. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time.

Let the researchers know if you choose to leave the study. Your choice will not affect any treatment relationship you have with healthcare providers.

Will being in this study help me in any way?

Being in this study may benefit from learning how to better talk to your healthcare provider about your pain. Even if the study does not help you directly, your participation

in this study may help other people in the future by helping us learn more about how we can improve communication about pain for non-English speaking Hmong patients.

What are the risks?

There is a risk that your information could become known to someone not involved in this study. Although this study does not assess emotional distress for you, it is possible that you may experience symptoms of emotional distress such as depression, suicidal thoughts, or anxiety. Because we are recording your conversations during the clinic, it is possible that there may be identifiable health information disclosed.

Will being in this study cost me anything?

There will be no cost to you for taking part in this research study.

Will I be paid or receive anything for being in this study?

We will pay you $50 for participating in this study. Payment will be provided at the end of the study visit. If you choose to leave before you complete the study visit, you will receive no payment.

How will researchers keep my research information confidential?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials and study sponsors responsible for monitoring the safety of this study. We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with other researchers without additional consent or authorization from you or your legally authorized representative.

The audio recordings of the conservation during the clinic visit will be kept indefinitely (banked), meaning we have no plan to destroy the recordings. The recordings may be used for future research. The recordings will be edited to remove all your identifying information before they are banked. They will not be used for purposes other than research.

Although we do not ask any questions about emotional distress, if you verbalized emotional distress such as depression or suicidal thoughts, we will provide you with a list of resources that you could use to seek out care. Specifically, if you disclose suicidal thoughts to a study team member, she or he will assess your intent and plan for suicide. If needed, the study team member will accompany you to the emergency room at the nearest hospital. The leader (PI) of the study will contact you immediately after the encounter to follow up. If you are expressing depression, you should contact your physician or other healthcare provider such as a mental health professional.

Who at UW-Madison can use my information?

- Members of the research team
- Offices and committees responsible for the oversight of research

The U.S. Office for Human Research Protections outside the UW-Madison may also receive your information.

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

Will information from this study go in my medical record?

None of the information we collect for this study will go in your medical record.

What if I have questions?

If you have questions about this research or you feel you have been harmed by participating in this study, please contact the Lead Researcher, Maichou Lor, at (608) 263-8009. If you have any questions about your rights as a research subject or have complaints about the research study or study team, contact UW Health Patient Relations at 608-263-8009. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.