NCT03982459

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

CC#14655: Acceptability and Effectiveness of a Novel Internet-Based Decision-Support Aid Based on the NCCN Non-Small Cell Lung Cancer Patient Guidelines

This is a research study to evaluate a decision-support aid to improve the decision-support process and experience for patients with non-small cell lung cancer (NSCLC). The study researcher, Sue S. Yom, M.D. and her associates from the University of California, San Francisco (UCSF) Helen Diller Family Comprehensive Cancer Center will explain the research study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you have been diagnosed with non-small cell lung cancer (NSCLC) and you are discussing therapy options.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to evaluate a decision-support aid, Patients with Power, developed for patients with non-small cell lung cancer (NSCLC). The researchers would like to learn more about whether this aid improves the decision-support process for patients.

The Patients with Power software will allow you to explore treatment options based on the National Comprehensive Cancer Network (NCCN) guidelines and the timing of therapies with the intent to help you discuss your treatment options with your oncologist. The software is based on a similar software concept that has been positively tested in the breast cancer community.

The National Comprehensive Cancer Network (NCCN) will provide funding for this study.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Up to 250 people may participate in the study at UCSF.

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

Before you begin the main part of the study...

If you agree, the following procedures will occur:

- Questionnaires - You will be asked to complete a series of questionnaires before and after you have received training about the Patients with Power software. The questionnaires will be used to evaluate your decision-support process, your ability to

perform everyday tasks, and assess your symptoms. The questionnaires will take approximately 1 hour to complete.

- Training to use the Patients with Power software – You will receive training from the study team about how to access and use the Patients with Power software online. The training will take approximately 15 minutes to complete.
- Access to Patients with Power software – Once you have received training to use the software, you will have unlimited access to the software indefinitely.
- Medical record review - Investigators will review your medical records for up to 12 months to gather information about your cancer treatment decisions.

Study location: The administration of questionnaires and software training will be done at the Helen Diller Family Comprehensive Cancer Center at UCSF. Access to Patients with Power software can be done from on any computer with internet access.

HOW LONG WILL I BE IN THE STUDY?

Participation in the study will take about 1-1.5 hours to complete the questionnaires and receive training for the software. Patients will be enrolled in this study for up to 12 months for data collection purposes and may participate in the study by using the Internet-based software as much as they want. You will have unlimited access to the software indefinitely.

CAN I STOP BEING IN THE STUDY?

Yes. You can decide to stop at any time. Tell the study researcher or staff person right away if you if you wish to stop being in the study.

Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

WHAT SIDE EFFECTS OR RISKS CAN I EXPECT FROM BEING IN THE STUDY?

Questionnaire risks: Answering the questionnaire may be an inconvenience. Some of the questions may remind you of unpleasant aspects of your therapy or disease, and you may experience some discomfort, anxiety or distress in answering such questions. You are free to decline to answer any questions you do not wish to answer, or to stop participating at any time.

Patients with Power software risks: The treatment information may produce unpleasant emotions or feelings, but you will be able to stop using the software at any time if you feel too uncomfortable.

For more information about risks and side effects, ask one of the researchers.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

There will be no direct benefit to you from participating in this study. However, the information that you provide may help health professionals better understand/learn more about the decision-support aid for patients with cancer.

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

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

WILL MY MEDICAL INFORMATION BE KEPT PRIVATE?

We will do our best to make sure that the personal information in your medical record is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The National Cancer Institute (NCI) and other government agencies, e.g., the Food and Drug Administration (FDA), involved in overseeing research
- The University of California
- Patients with Power IT Software Support Personnel

Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. A medical record will be created because of your participation in this study. Your consent form and some of your research test results will be included in this record. Therefore, your other doctors may become aware of your participation. Hospital regulations require that all health care providers treat information in medical records confidentially.

If you choose to establish a Patients with Power (PwP) account, the IT software support personnel from PwP may need access to some of your information as part of their administration of software problems and debugging. If you elect to have a permanent PwP account, you will make an Internet based account. Similar to any other cloud based account (for example: a Google account, Facebook account), the information you enter will be accessible to high level IT administrators on the PwP team.

You will be asked to agree to the terms and conditions of the PwP site before creating an account.

You are not required to put in any private health information into the PwP program, or any personally identifiable information into the program. If you choose not to make an account, we can still provide access to the program for you during your consultation. In that case, however, you will not be able to go back later and look at the information yourself and you will not have a permanent PwP account created for you.

WHAT ARE THE COSTS OF TAKING PART IN THE STUDY?

You will not be charged for any of the study procedures.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

You will not be paid for taking part in this study.

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

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

You can talk to the study researcher about any questions, concerns, or complaints you have about this study. Contact the researcher, Sue S. Yom MD, [redacted].

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Office of the Committee on Human Research at 415-476-1814.

CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

_____ _____

Participant Date

_____

Participant name (print)

_____ _____

Person obtaining consent	Date

Person obtaining consent (print)