

Document Type: Informed Consent Form - Caregiver

Title: A pilot randomized controlled trial of a patient-centered communication tool (UR-GOAL) for older patients with acute myeloid leukemia, their caregivers, and their oncologists

NCT number: NCT05335369

Document Date: December 13, 2023

CAREGIVER CONSENT FORM

A pilot randomized controlled trial of a patient-centered communication tool (University of Rochester-Geriatric Oncology Assessment for acute myeloid Leukemia or UR-GOAL) for older patients with acute myeloid leukemia, their caregivers, and their oncologists

Principal Investigator:
Kah Poh (Melissa) Loh, MD, MS

This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully.

The study staff will explain this study to you. Please ask questions about anything that is not clear before you agree to participate or at any time. You may take this consent form home to think about and discuss with family or friends.

Key Information

- Being in this research study is voluntary – it is your choice.
- You are being asked to take part in this study because you have been identified as a caregiver to a patient who is 60 or older and has a new diagnosis of acute myeloid leukemia (AML) or are being worked up for possible AML.
- The purpose of this study is to test whether a communication tool helps with treatment decision making and communication between individuals with AML and their oncologist
- Your participation in this study will last about 1-2 months.
- Procedures may include completing surveys, watching an education video, helping patients use a communication tool, and completing follow-up questionnaires to assess your experience in the study.
- There are risks from participating
 - The most common risk from participating is loss of confidentiality.
 - See the “Risks of Participation” section in this consent form for more information. You should discuss these risks in detail with the research team.

Introduction

You are being asked to take part in this study because you have been identified as a caregiver to a patient who is 60 or older and has a new diagnosis of acute myeloid leukemia (AML) or is being worked up for a possible AML. This form describes the known possible risks and benefits of the study. You are completely free to choose whether or not to participate in this study.

Older adults with AML may feel inadequately informed about their AML diagnosis and treatment options. Incorporation of a communication tool may help older adults better understand their diagnosis and treatment options in order to facilitate improved communication with their oncologist.

This study is being conducted by Dr. Kah Poh (Melissa) Loh from the University of Rochester's Division of Hematology/Oncology.

Purpose of Study

The purpose of this study is to test whether a communication tool (UR-GOAL) helps with treatment decision making and communication between individuals with AML and their oncologists.

Description of Study Procedures

Patients will be randomly assigned to one of two groups. Randomization means that the group the patient is in is assigned by chance, like the flip of a coin. The patient's chance of being in each group is equal.

If you decide to take part in this study, you will be asked to:

- Complete questionnaires asking questions about your demographics, health problems, mood, and disease understanding. These forms will take you approximately 10 minutes to complete.
- Within 4 weeks after the patient's treatment start, we will ask you complete post-intervention surveys.

If the patient is assigned to Group 1 (UR-GOAL):

- You will watch a short AML educational video and you may help the patient use the communication tool if needed.
- The tool will provide a summary report for the patient and oncologist prior to discussion of AML treatments. You may read the summary report as well.
- Within 4 weeks after the patient's treatment start, we will ask you to participate in an audio-recorded interview during which we will ask you about communication with the oncologist. We will also get your feedback regarding the AML educational video and communication tool.

If the patient is assigned to Group 2 (control):

- You will meet with the patient's oncologist as usual and discuss AML treatments.
- Within 4 weeks after the patient's treatment start, we will ask you to participate in an audio-recorded interview during which we will ask you about communication with the oncologist.

The patient may still participate if you (the caregiver) decide to not participate in the study.

Number of Subjects

Approximately 100 patients and their caregivers will take part in the study.

Duration of the Study

Your participation in this study will last approximately 1-2 months.

Sponsor Support

The University of Rochester is receiving funding from the *Conquer Cancer®*, the *American Society of Clinical Oncology (ASCO)*, and the *American Cancer Society®* for conducting this research study.

Costs

There will be no cost to you to participate in this study.

Payments

You will not receive any payment for your participation in this study.

Benefits of Participation

You may not benefit from being in this research study.

Risks of Participation

The study has minimal risk. While we will make every effort to keep information we learn about you private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law.

The risk associated with this study includes loss of privacy and confidentiality because we will collect personal data from you. Personal data will be kept as confidential as it can be, but complete confidentiality cannot be guaranteed.

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.

Version Date: 12/13/2023
PRMC#: UOCPC22010
Caregiver Informed Consent
ClickIRB#: STUDY00007102

Confidentiality of Records

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will keep all information you provide to us in locked filing cabinets in a locked office and electronic data will be kept in a password-protected and secure database. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor. If this does happen, we will take precautions to protect the information you have provided.

Results of the research may be presented at meetings or in publications, but your name will not be used.

Audio-recorded interviews will be transcribed by a professional transcription service called ExecuScribe. Both the audio-recorded interviews and interview transcripts will be kept for a period of 7 years after the study and all reports and publications are complete. If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?

The study doctor will get your personal and research information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits

Who may use and give out information about me?

- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester
- ExecuScribe (for the purpose of transcription)

Why will this information be used and/or given to others?

- To do the research
- To study the results
- To see if the research was done right

What if I decide not to give permission to use and give out my health information?

- Then you will not be able to be in this research study.

May I review or copy my information?

- Yes, but only after the research is over.

How long will this permission be valid?

- This permission will last indefinitely.

May I cancel my permission to use and disclose information?

- You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

How long will my health information be kept?

- We will keep your information for 7 years after study completion. Your information will be destroyed after.

May I withdraw from the study?

- Yes, you may withdraw from the study. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

- No. There is a risk that your information will be given to others without your permission. Once your information is disclosed to the named entities or organizations listed above, it is possible that your information will be re-disclosed and will no longer be protected by U.S. federal privacy regulations.

Use of E-mail for Communication in Research

You may receive communication about this study via email.

Email communications may be used to complete baseline and post-intervention activities, schedule study visits, and schedule your end-of-study interview. You may be sent reminder emails to complete tasks. Documents may be sent to you via email for your records.

Email communications may be sent or received in an unencrypted (unprotected) manner. Therefore, there is a risk that the content of the communication, including your personal information, could be shared beyond you and the research team. Your consent below indicates that you understand this risk. The University of Rochester is not

responsible for any interception of messages sent through email. Email communications between you and the study team may be filed in your research record.

Contact Persons

For more information or questions about this research you may call Dr. Kah Poh Loh at 585-276-4353 or the study coordinator at (585) 602-5082.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

*******End of Section*******

Signature/Dates

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Caregiver Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

Caregiver Name (Printed by Caregiver)

Signature of Caregiver

Date

Person Obtaining Consent

I have read this form to the patient and/or the patient has read this form. I will provide the patient with a signed copy of this consent form. An explanation of the research was given and questions from the patient were solicited and answered to the patient's satisfaction. In my judgment, the patient has demonstrated comprehension of the information. I have given the patient adequate opportunity to read the consent before signing.

Name and Title (Print)

Signature of Person Obtaining Consent

Date