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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

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PATIENT 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 are aged 60 or older and have 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 like yourself and your oncologist.
- Your participation in this study will last about 6-7 months.
- Procedures may include watching an education video, using a communication tool, and completing follow-up surveys 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 are aged 60 or older and have a diagnosis of new acute myeloid leukemia (AML) or are being worked up for 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.

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

Purpose of Study

Older adults with AML may feel inadequately informed about their AML diagnosis and treatment options. The incorporation of a communication tool may help older adults better understand their diagnosis and treatment options to facilitate communication with their oncologist. The purpose of this study is to test whether a communication tool (UR-GOAL) helps with treatment decision-making and communication between individuals like yourself and your oncologist.

Description of Study Procedures

If you decide to take part in this study, you will be randomly assigned to one of two groups:

- Group 1: UR-GOAL (intervention)
- Group 2: Standard of care (control)

Randomization means that the group you are in is assigned by chance, like the flip of a coin. Your chance of being in each group is equal, and you will be told which group you are in.

Once we confirm that you are eligible for the study and that you have agreed to participate in the study, you will be asked to do the following no matter what group you are assigned to:

- Complete a physical performance test in which we will test your balance, walking speed, and ability to stand unassisted.
- Complete a brief memory and concentration test
- You will be provided a packet of surveys asking questions about your demographics, physical function, mood, social support, disease understanding, and decision-making preferences. These forms can be completed at your own pace but should take no more than 20 minutes if completed all at once.
- Within 4 weeks after you have made a treatment decision with your oncologist, we will ask you to participate in an audio-recorded interview during which we will ask you about communication with your oncologist.
- 3 and 6 months after you have made a treatment decision, you will be provided surveys asking about how you feel about that decision and your current quality of life. These forms should take no more than 15 minutes to complete each time.
- You can participate without a caregiver but may also choose a caregiver to participate. If your caregiver has agreed to participate in the study, we will ask your caregiver to participate in an audio-recorded interview during which we will gather feedback. If your chosen caregiver was at the clinic visit, we will ask them about communication with the oncologist.

If you are assigned to Group 1 (UR-GOAL):

- You will watch a short AML educational video and use the communication tool
- The tool will provide a summary report for you and your oncologist before the discussion of AML treatments.
- At the audio-recorded interview we will also get your feedback regarding the AML educational video and communication tool in addition to asking you about communication with your oncologist
- You complete a short version of the communication tool at 3 and 6 months

If you are assigned to Group 2 (control):

- You complete the short version of the communication tool.
- You will meet with your oncologist as usual and discuss AML treatments.

Number of Subjects

Approximately 100 patients will take part in the study.

Duration of the Study

Your active participation in this study will last 6-7 months. For us to complete the study and understand the results, we will need to access information from your medical record for up to 7 years after you complete the study.

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 be paid $50.00 for taking part in this study. You will be paid once you have completed the post-intervention surveys.

For this study, we use a subject payment system called Participant Payments. The system allows three ways to provide payment. You can choose: a reloadable debit card, direct deposit, or mailed paper checks. The study team will help you create a "subject profile" in the system. In order to provide payment, you will need to enter your name and date of birth into your subject profile. Depending on which payment method you choose, you may also need to enter your email address and banking information. If you already have a Participant Payment account (because you are in another study that uses this system), your existing profile will be used to provide payment. See the '**Information Sheet for Participant Payments**" provided with this consent for additional information.

Payment received for participation in research is considered taxable income. If you receive $600.00 or more in any one calendar year from UR or its affiliates, the University is required to report this information to the Internal Revenue Service (IRS) in a 1099 (Miscellaneous Income) form. You will be sent a copy of this form and a copy will be sent to the IRS. Depending on the amount you are paid, you may be asked to submit a W-9 form, which includes your Social Security Number. If you are asked to complete a W-9 form and we find that you are not a US citizen or permanent resident, we may need to withhold 30% of your payment for taxes consistent with tax requirements.

Benefits of Participation

You may not directly benefit from being in this research study.

Risks of Participation

The study has minimal risk. While we will make every effort to keep the 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. There is a risk of loss of confidentiality and privacy because we will collect medical and personal data from you and your medical record. Protected health data and personal data will be kept as confidential as they can be but complete confidentiality cannot be guaranteed.

eRecord, MyChart, and your participation in this study:

Taking part in this study may be documented in your electronic health record (eRecord), and you and your designated proxies may see the results in MyChart. The following individuals may know you participated in this research study:

- Staff at the University of Rochester Medical Center and its Affiliates (e.g., Strong Memorial Hospital, Highland Hospital, URMC primary care, specialist physician offices) who have a reason to access your electronic health record.
- Health care providers who are involved in your care at a facility that is not part of the University of Rochester Medical Center and its Affiliates and who have reason to access your electronic health record.
- Individuals who request a copy of information from your health record for activities such as treatment or payment (e.g., medical insurance companies, worker's compensation).
- The study team may be notified if you receive other health care services at URMC or any of its Affiliates (e.g., visit to the emergency room or urgent care).

If you have questions or concerns, you should discuss it with the study team.

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.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

Because this study involves collecting personal, identifiable information about you, there is a potential for invasion of privacy or breach in confidentiality. The University of Rochester will make every effort to keep the information collected from you private. To minimize this risk, we will assign you a study number instead of labeling the information we collect from you with your name or medical record number. All of the information we collect will be stored securely and only study team members will have access to it.

Sometimes researchers need to share information that may identify you with people that work for the University. If this does happen we will take precautions to protect the information you have provided.

Results of the research may be presented publicly at meetings or in publications, but your name or identifying information 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 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.

In order to collect study information, we have to get your permission to use and give out your personal health information.

What information may be used and given to others?
The study doctor and study coordinators will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Past and present medical records related to the study

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
- Participant Payment Systems (for the purpose of registering you for payment)
- ExecuScribe (for the purpose of transcription)
- Sawtooth (the UR-GOAL communication tool)

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 medical 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 research team may be filed in your research record.

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. If you do withdraw from this study, the information you have already provided will be kept confidential.

Contact Persons

For more information concerning this research or if you feel that your participation has resulted in any emotional or physical discomfort please contact: Dr. Kah Poh (Melissa) Loh at (585) 275-5863. For questions about this study please contact 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.

**********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.

Subject 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.

_____

Subject Name (Printed by Subject)

_____ _____

Signature of Subject Date

Person Obtaining Consent

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

_____

Name and Title (Print)

_____ _____

Signature of Person Obtaining Consent Date