THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Feasibility of positive activities in collectivist culture cancer patients

2020-0789

Subtitle: QualPAC: Quality of Life of Cancer Patients and Caregivers

Study Chair: Qian Lu, Ph.D.

_____ _____
Participant's Name Medical Record Number or Study ID

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

STUDY SUMMARY

The goal of this research study is to learn if performing certain simple activities can help to improve the quality of life of cancer patients and their caregivers.

This is an investigational study.

Taking part in this study may result in improved quality of life for you and your caregiver. Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including time commitment.

You can read a list of potential risks below in the Possible Risks section of this consent.

You will be on this study for about 6 weeks.

This study will be performed at no cost to you.

You may choose not to take part in this study.

1. STUDY DETAILS

Up to 104 participants will be enrolled in this study. All will take part at MD Anderson.

If you agree to take part in this study, you will be randomly assigned to 1 of 3 study groups. If you are a patient, you may engage in a study activity. If you are a caregiver, you may be the recipient of the study activity.

Neither you nor the researcher will choose what intervention you get. You will not be told which intervention group you are in until the end of the study.

If you are a patient, you will complete 3 questionnaires that have questions about your personal information (such as your age, race, and income) and questions about how you are feeling. These questionnaires will take about 20 minutes each time (before the study intervention, during the study intervention, and after the study intervention).

If you are a caregiver, you are encouraged to complete these questionnaires for the most complete data collection and contribution to science, but you have the option not to complete them should you choose not to.

You may also be chosen at random to take part in a 30-minute interview about your experiences with the study activity. The study staff will tell you if this applies to you and will provide additional information.

You will do all study questionnaires online using a secure website set up for this study and you will be asked to complete the study questionnaires in a private setting away from the other person in your household who is part of the study so that your answers do not influence one another. Your responses to the questionnaires will be kept confidential by the researchers and will not be shared with the other person in study. The interview may be done at MD Anderson or over the phone/Zoom.

2. POSSIBLE RISKS

Questionnaires and interviews may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact your doctor or the study chair.

You may experience some distress when participating in the study activities or answering questions about your emotional state, but this distress should be no greater than what you experience in everyday life.

If you are found to be under severe distress, emotionally or physically, during the course of the study, we will report your symptoms to your doctor/medical provider. This will also be communicated to you so that you may also report your symptoms to your doctor/medical provider.

This study may involve unpredictable risks to the participants.

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Unless otherwise stated in this consent form, all of the costs linked with this study, which are not covered by other payers (health maintenance organization [HMO], health insurance company, etc.), will be your responsibility, including costs incurred from contacting you via phone, video, or text messaging.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

If you are a patient, you may receive up to $100 as compensation for your time and efforts in the study. You will be paid $25 after the completion of the midpoint surveys at Day 14 and the other $50 after Day 28. If you are selected (at random) for an interview, you will be paid an additional $25 after the completion of the interview. If you withdraw from the study early, you will be paid $50 if you withdraw after Day 14 but before Day 28 and will not be paid if you withdraw prior to Day 14. If you are a caregiver, you may receive up to $25 for your participation in the study and will be paid after Day 28 if you are not selected for an interview and after the interview if you are selected for it.

Additional Information

4. You may ask the study chair (Dr. Qian Lu, at 626-467-3383) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you withdraw from this study, you can still choose to be treated at MD Anderson.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair or the IRB of MD Anderson.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

8. MD Anderson may benefit from your participation and/or what is learned in this study.

Future Research

Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and/or shared with other researchers and/or institutions for use in future research.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or research samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson may be collecting and using your PHI. For legal, ethical, research, and safety-related reasons, the research team may share your PHI with:
   - The Office for Human Research Protections (OHRP)
   - The IRB and officials of MD Anderson
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   If you are a patient, PHI may be collected from your medical record if you choose to take part in this study, including your date of birth, race/ethnicity, sex/gender, cancer

diagnosis and stage, date of diagnosis, language preference, contact information (e.g., email address), and main cancer doctor (primary medical oncologist).

B. Signing this consent and authorization form is optional but you cannot take part in this study if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible according to state and federal law. However, in some situations, health authorities could be required to reveal the names of participants.

   Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer of MD Anderson at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. 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.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

LEGALLY AUTHORIZED REPRESENTATIVE (LAR)

The following signature line should only be filled out when the participant does not have the capacity to legally consent to take part in the study and/or sign this document on his or her own behalf.

_____ _____
SIGNATURE OF LAR DATE

_____
PRINTED NAME and RELATIONSHIP TO PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol **2020-0789**.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for vulnerable adult participants. If witnessing the assent of a pediatric participant, leave this line blank and sign on the witness to assent page instead.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into_____and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

_____ _____ _____
NAME OF TRANSLATOR SIGNATURE OF TRANSLATOR DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line below.)

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION DATE
(OTHER THAN TRANSLATOR, PARENT/GUARDIAN,
OR STUDY CHAIR)

_____
PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION