Participant Informed Consent for Clinical Research

Study title for participants: A Study Comparing Two Types of Supportive Interventions for Caregivers of Patients with Cancer

Official study title for internet search on http://www.ClinicalTrials.gov: A Randomized Controlled Trial of Emotion Regulation Therapy for Cancer Caregivers: A Mechanism-Targeted Approach to Addressing Caregiver Distress

Subtitle: Caregiver Consent

Lead Researcher: Christian Nelson, PhD (646-888-0030)

Overview and Key Information

Why is this study being done?

We are asking you to take part in a clinical research study. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

You are being asked to participate because you are caring for a family member or friend who has been diagnosed with cancer.

Caregivers of cancer patients often experience high levels of distress related to their loved one's diagnosis and the course of their loved one's disease. Symptoms of distress may include anxiety and depression. Studies have shown that caregivers of cancer patients can benefit from supportive interventions that focus on helping them to cope with their emotions to better care for their loved one and themselves. Researchers are exploring new ways to treat caregiver distress.

We are doing this study to compare two types of supportive interventions for caregivers of cancer patients: Emotion Regulation Therapy for Cancer Caregivers (ERT-C) and Cognitive Behavioral Therapy for Cancer Caregivers (CBT-C).

CBT is a common form of psychotherapy, and researchers have studied it in caregivers. CBT helps people become aware of inaccurate or negative thinking so they can view difficult situations more clearly and respond to them in a more effective way. The researchers adapted CBT for caregivers of patients with cancer, called CBT-C. ERT-C is a type of CBT that was created for caregivers of patients with cancer to help them recognize and gain control over the negative emotions that arise as a result of caregiving.

During this study, we will see if ERT-C is better than, the same as, or worse than CBT-C at improving caregiver distress. We will also enroll cancer patients to see how their caregivers' participation in ERT-C or CBT-C may affect the patients' quality of life, stress, and use of healthcare services.

We will ask the patient you care for to participate, but that person does not have to be in the study in order for you to participate.

Taking part in this study is your choice.

You can choose to take part or not to take part in this study, and you can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document presents important information to help you make your choice. Please take time to read it carefully. Talk with your doctor, family, or friends about the risks and benefits of taking part in this study. It's important that you have as much information as you need, and that all your questions are answered.

What is the usual approach to treating my caregiver distress?

People who are not participating in a research study can seek support or information from a nurse or other professional to help them with their caregiving responsibilities and any distress those responsibilities may cause.

What are my other choices if I decide not to take part in this study?

- You may choose to have the usual approach described above
- You may choose to take part in a different research study, if one is available

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will receive 8 counseling sessions of either ERT-C or CBT-C over 8-16 weeks. The counseling sessions will be conducted remotely (for example, using video conferencing, such as Webex or Zoom). You will also complete questionnaires about yourself, your health, and your experience caring for your loved one.

After you finish ERT-C or CBT-C, you will complete questionnaires 3 and 6 months after your last session. After this, your participation in the study will be complete.

Throughout the study, you will collect your saliva. We will use your samples to measure hormone and stress levels. You will find more information about saliva collection in the section *What extra tests and procedures will I have if I take part in this study?*

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important to think carefully about these as you make your decision.

Risks

We want to make sure that you know about a few key risks right now. We will also give you more information in the *What risks can I expect from taking part in this study?* section of this consent form.

There is no physical risk involved in participating in this study, but filling out the questionnaires and participating in the counseling sessions may make you feel uncomfortable, stressed, or upset. Please note that you are not required to answer any questions that cause you to feel uncomfortable, stressed, or upset.

Benefits

Studies in caregivers of cancer patients have shown that psychotherapy (including CBT-C) can help treat distress. Whether you receive ERT-C or CBT-C during this study, the therapy may help your

distress, or your distress may stay the same, or even get worse. What we learn from the study may help other people in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop participating in the study at any time.

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

If you decide to stop, let the study doctor know as soon as possible. If you stop, we will not be able to withdraw information about you that has been used or shared with others before you informed us of your decision to stop. If you wish to discontinue treatment before completing all 8 counseling sessions, you will be given the option to remain on study to complete follow-up assessments.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes, and the study is no longer in your best interest
- New information becomes available, and the study is no longer in your best interest
- You do not follow the study rules
- The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), Food and Drug Administration (FDA), or the study sponsor, Memorial Sloan Kettering Cancer Center (MSK). The study sponsor is the organization that oversees the study.

It is important that you understand the information in this informed consent document before you make a decision about participating in this clinical trial. Please read, or have someone read to you, the rest of this document. If there is anything that you don't understand, ask the study doctor or nurse for more information.

What is the purpose of this study?

The purpose of this study is to compare two types of therapy for caregivers of cancer patients: Emotion Regulation Therapy for Cancer Caregivers (ERT-C) and Cognitive Behavioral Therapy for Cancer Caregivers (CBT-C). The researchers want to see if ERT-C is better than, the same as, or worse than CBT-C at improving caregiver distress. We will look at how the two types of therapy affect caregivers' anxiety, depression, and quality of life. We will also see how ERT-C and CBT-C affect hormone and stress levels in caregivers' saliva samples.

In addition, we will enroll cancer patients in this study to see how their caregivers' participation in ERT-C or CBT-C may affect the patients' quality of life, stress, and use of healthcare services.

The results of this study will help researchers learn more about psychotherapeutic approaches to caregiver distress. If caregivers can develop the needed skills for coping with their emotions, they can better care for their loved one and themselves.

About 480 people (240 caregivers and 240 patients) will take part in this study. About 260 people will take part in this study at Memorial Sloan Kettering Cancer Center (MSK).

What are the study groups?

This study has two study groups: one for caregivers and one for cancer patients who have a caregiver. You are being asked to participate in the caregiver group.

- Participants in the **caregiver group** will receive either ERT-C or CBT-C. A computer will assign you by chance to ERT-C or CBT-C. This process is called randomization, and it is done by chance because no one knows whether one type of therapy is better than the other. You have a 1 in 2 chance of being randomized to either therapy. The study doctor will tell you which therapy you will receive. Participants in the caregiver group will also fill out questionnaires about themselves and their experience caring for their loved one.

- Participants in the **cancer patient group** will complete questionnaires about themselves, their health, and their use of healthcare services

What extra tests and procedures will I have if I take part in this study?

Before you begin the main part of the study:

The study coordinator will review your medical records and ask you questions to determine if you can take part in the study. This first part of the study is called screening. If you join the study, you will complete questionnaires about yourself and your health. Filling out these questionnaires will take about 4 minutes.

The questionnaires that are part of this study are electronic, and you will complete them either at the clinic or at home. If you are not able to complete the questionnaire electronically, you can fill them out on paper at the clinic or you can give your answers to a member of the study team over the phone.

During the study:

Depending on which group you are assigned to, you will receive 8 counseling sessions of either ERT-C or CBT-C. You will receive ERT-C or CBT-C once a week for 8 weeks. If your schedule changes, you can move your session. We ask that you complete all 8 sessions within 16 weeks of when you start the study.

The counseling sessions will be via telepsychiatry (for example, using video conferencing, such as Webex or Zoom). Each session will last about 60 minutes, and sessions will be audio and video recorded. We may use audio/video clips of some of these recordings for academic, educational, or training purposes. We will ask you to sign a separate authorization form before using your recordings for these purposes.

<u>Exams, Tests, and/or Procedures</u>

You will have questionnaires and saliva tests during the main part of the study. The procedures that will be done only for research purposes, or that may be done more often because you are participating in this study, are listed below.

- You will complete questionnaires at baseline (before your first session) and after you finish your last session (within 1 week). Filling out these questionnaires will take between 60 and 90 minutes each time. You will also complete questionnaires on the day of each session; filling out these questionnaires will take about 15 minutes each time. You will be asked questions about yourself, your health, and your experience as a caregiver.

- Saliva collection at baseline and the day after your last session to measure hormone and stress levels. You will swab from inside the cheek of your mouth to collect saliva samples 4 times each day for 3 days in a row. You must avoid brushing your teeth, eating, or drinking within 20 minutes before you swab. You will swab at the following times each day:
    - After you wake up but before you get out of bed
    - 30 minutes after you wake up
    - 8 hours after you wake up
    - Just before you go to bed

A member of the study team will give you saliva collection instructions and a diary, so that you can write down when you collect your saliva samples. You will also record health behaviors (such as caffeine, tobacco, and alcohol use; physical activity; and sleep). Instructions about how to collect your saliva samples are included in the diary. The study team will also provide instructions about how to return your samples to the study team.

Follow-up visits:

You will have follow-up questionnaires and saliva tests at two additional timepoints: 3 and 6 months after your last counseling session.

- You will complete questionnaires about yourself, your health, and your experience as a caregiver. Filling out these questionnaires will take between 1 and 2 hours each time.
- Saliva collection 4 times each day for 3 days in a row. You must avoid brushing your teeth, eating, or drinking within 20 minutes before you swab. You will swab at the following times each day:
    - After you wake up but before you get out of bed
    - 30 minutes after you wake up
    - 8 hours after you wake up
    - Just before you go to bed

A Study Calendar that shows how often you will have these exams, tests, and procedures is provided at the end of this consent form. The calendar also includes exams, tests, and procedures that are part of your usual care.

Will I receive the results of my research tests?

You will not receive the results of any tests done for research purposes during this study.

What risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that:

- You may lose time at work, school, or at home, and you may spend more time than usual in the hospital or doctor's office
- You may be asked sensitive or private questions that you do not usually discuss

There are no physical risks involved in participating in this study. You may feel uncomfortable, stressed, or upset when you are filling out the questionnaires or participating in the counseling sessions. You do not have to answer any questions that cause you to feel uncomfortable, stressed, or upset. If you become very upset while you are taking part in this study, we can give you a list of counseling resources that might be helpful.

MSK will protect your personal information (data), so that your name and any other identifying information will be kept private. The chance that your information will be given to anyone other than the people or organizations named in the Research Authorization form (below) is very small.

Let the study doctor know about any questions you may have about possible risks of taking part in this study.

What are my responsibilities in this study?

If you choose to take part in this study, you will need to:

- Keep your study appointments
- Remember to bring your completed saliva collection diary to your clinic appointments
- Let the study doctor know if you skipped or chose not to answer any of the questions in the questionnaire/survey

Is there a conflict of interest for this study?

This study is sponsored by Memorial Sloan Kettering Cancer Center (MSK) and funded by the National Cancer Institute (NCI). There are no known investigator and/or institutional conflicts of interest for this study.

What are the costs of taking part in this study?

You will not have to pay for the study intervention or for tests and procedures done only for research purposes, including:

- Saliva collection

You and/or your health plan/insurance company will have to pay for all the other costs your health care while you are participating in this study.

Will I receive payment for taking part in this study?

You will receive a payment of up to $130 in electronic or physical gift cards or money orders for taking part in this study. Payment will be given at the following times:

- Baseline (before your first ERT-C or CBT-C session): $5
- At the completion of each ERT-C or CBT-C session: $10 at each session
- Once you complete all ERT-C or CBT-C sessions: $10
- 3-month follow-up: $15
- 6-month follow-up: $20

Who will see my medical information?

Your privacy is very important to us, and the researchers will make every effort to protect it. Trained staff at Memorial Hospital may review your records, if necessary.

Access to your protected health information will be limited to those listed in the Research Authorization form, which is a part of the informed consent process.

Your information may be given out, if required by law. For example, some states require doctors to make a report to the state health board if they find that a participant in a research study has a

contagious disease like tuberculosis. However, the researchers will do their best to make sure that any information about you that may be released will not identify you.

In the future, your information (data) and biospecimens may be de-identified, which means that your data and/or biospecimens will be assigned a unique code, and the list that links the code to your name will be stored separately from your biospecimens and data. Your de-identified information and biospecimens may be used for research that has not been described in this consent form, and they may be shared with another investigator for future research. You will not be asked if you agree to take part in future research studies.

If your information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. It is possible that your de-identified information from this study will be shared with other researchers outside of MSK, and may be stored in public databases related to research. All requests for data sharing will be reviewed by the study sponsor, and if individual results are included in the data, they will not contain any identifiable information about you, such as your name, address, telephone number, or social security number. Your privacy is very important to us and we use many safety procedures to protect your privacy. However, we cannot guarantee that no one will ever be able to use your information to identify you.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about research studies, or for general information about cancer. You may also call the NCI Cancer Information Service to get the same information at 1-800-4-CANCER (1-800-422-6237).

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.

You can talk to the study doctor about any questions or concerns that you may have about this study, or to report side effects or injuries. You may also contact the lead researcher listed on the first page of this consent.

For questions about your rights while you are participating in this study, call the MSK Institutional Review Board (IRB) at 212-639-7592. If you have concerns, complaints, or input on research, or if you would like more information about the informed consent process, please contact the MSK Patient Representative Department at 212-639-7202.

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

A Study Comparing Two Types of Supportive Interventions for Caregivers of Patients with Cancer

Federal law requires Memorial Sloan Kettering Cancer Center (MSK) to protect the privacy of information that identifies you and relates to your past, present, and future medical conditions (protected health information; PHI). We are committed to protecting the privacy of your information.

If you enroll in this research study, your protected health information will be used and shared with others, as explained below. MSK must obtain your permission before using or sharing your protected health information for research purposes. This form helps to make sure that you are informed of the ways in which your information will be used or shared in the future.

Carefully read the information below before you sign this form. By signing this form, you agree to the use and disclosure of your information for this research study.

1. What protected health information about me will be used or shared with others during this research?

- Your medical records
- Your research records, including new health information created from study-related tests, procedures, visits, and/or questionnaires
- Any health information or clinical data associated with your biospecimens, if the information or data could be reasonably used to identify you. This information or data will be shared only if you have agreed to it by signing this informed consent document.
- HIV-related information, including any information indicating that you have had an HIV-related test; or that you have HIV infection, HIV-related illness, or AIDS; or any information that could indicate that you may have been exposed to HIV. (New York State requires us to obtain your consent to use or share this information.)

2. Who will use or share my protected health information?

MSK will use and share your protected health information. People and offices that deal with research oversight, quality assurance, and/or billing will be able to use and share your protected health information, including:

- The study's Principal Investigator and Co-Principal Investigator: Christian Nelson, PhD and William Breitbart, MD
- Your research team at MSK, including the participating investigators, research staff, research nurses, fellows/residents, and clerical support staff
- Any healthcare personnel who provide services to you in connection with this study
- Members and staff of MSK's Institutional Review Board (IRB) and Privacy Board (PB)
- Staff of MSK's Clinical Research Administration, which oversees clinical studies, and Clinical Research Information Technology Group, which manages research databases
- Members of MSK's Data Safety Monitoring Board/Committee and the Quality Assurance Committee

3. With whom outside of MSK may my protected health information be shared?

Although all reasonable efforts will be made to maintain the confidentiality of your protected health information, it may be shared with and used by the following:

- The company or organization that provides the funding for the study, the National Cancer Institute (NCI).
- MSK's research collaborators, business partners, subcontractors and agent(s), in the United States or in other countries, working to conduct the study, to monitor the study, or to analyze the study information for this study or for other research about the study intervention.
- Other research doctors and medical centers participating in this research.
- Federal and state agencies, and other domestic or foreign government bodies, if required by law and/or necessary for oversight purposes, including:
    - Office for Human Research Protections (OHRP) of the US Department of Health and Human Services (HHS)
    - US Food and Drug Administration (FDA) and other regulatory agencies responsible for oversight of research
    - National Cancer Institute (NCI)/National Institutes of Health (NIH)
- Other qualified researchers, approved by Memorial Sloan Kettering Cancer Center, who may receive individual research results that do not identify you.

Some of the organizations that may receive your protected health information may not have to satisfy the privacy rules and requirements; they may share your information with others without your permission.

4. Why will my protected health information be used by or shared by MSK or others?

The main reasons for the use or sharing of your information include the following:

- To conduct the study, to monitor your health status, to measure the effects of the drug(s)/device(s)/procedure(s) being studied, and to determine the research results
- To ensure that the research meets legal and institutional requirements
- To develop new tests, procedures, and commercial products
- To enhance research databases, so that scientists can design better research studies to develop new therapies for patients and to gain a better understanding of disease
- To assist with MSK medical treatment, billing, or healthcare operations. For example, medical information produced by this research study will become part of your hospital medical record.

5. For how long will my protected health information be used or shared with others?

There is no set date at which your protected health information that is being used or shared for this research study will be destroyed or no longer used. The information used and created during the

study may be analyzed for many years, and it is not possible to know when this analysis will be completed.

6. Statement of privacy rights:

- It is your right to refuse to sign this authorization form. If you do not sign this form, you will not be able to participate in this research study. However, if you do not sign, it will not affect your ongoing medical treatment or healthcare coverage.

- You have the right to withdraw your permission for MSK to use or share your protected health information. Please note that we will not be able to withdraw all the information about you that already has been used or shared with others to carry out research-related activities such as oversight, or information that is needed to ensure the quality of the study. To withdraw your permission, write to the study doctor listed on the first page of this consent form at: Memorial Sloan Kettering Cancer Center, 1275 York Avenue, New York, NY 10065. If you withdraw permission for us to use or share your protected health information, you will not be able to continue to participate in this research study.

- You have the right to request access to your protected health information that is being used or shared during this research and that is related to the research or to payment for the research. However, you may access this information only after the study is completed. You may have access to the parts of your medical record that are unrelated to this study at any time. To request this information, please contact the study doctor whose name and telephone number are listed on the first page of this consent form. You may also ask the study doctor to correct any study-related information about you that is wrong.

Notice concerning HIV-related information

Individuals/organizations are prohibited from sharing any HIV-related information about you without your approval, unless they are permitted to do so under federal or state law. You have a right to request the list of people who may receive or use your HIV-related information without your authorization.

If you experience discrimination because of the release or disclosure of your HIV-related information, you may contact the New York State Division of Human Rights at 888-392-3644 or the New York City Commission on Human Rights at 212-306-7500. These agencies are responsible for protecting your rights.

Participant Informed Consent/Research Authorization for Clinical Research

Statement of professional obtaining consent

I have fully explained this clinical research study to the participant. In my judgment, and in that of the participant, sufficient information, including risks and benefits, was provided for the participant to make an informed decision. The consent discussion will be documented in the participant's EMR.

Consenting professional must personally sign and date		
Consenting professional's signature		**Date:**
Consenting professional's name (Print)		

Participant's statement

I have read this form that describes the clinical research study. I have also talked it over to my satisfaction with the consenting professional. By signing below, I agree to the following: (1) to voluntarily participate in this clinical research study; (2) to authorize the use and disclosure of my protected health information (data about myself); and (3) to state that I have received a signed and dated copy of this consent form.

Participant must personally sign and date		
Participant signature		**Date:**
Participant name (Print)		

Witness signature (if required)

- ❑ Witness for non-English speaking participant: I declare that I am fluent in both English and in the participant's language, and I confirm that the consent discussion was appropriately interpreted for the participant.
- ❑ Other: I confirm that the consent discussion occurred, and that the participant agreed to participate in this study by signing this form, making his/her mark, or verbally agreeing.

Name of witness: _____

Signature of witness: _____ **Date:** _____

(The name of the witness must be documented in the EMR.)

Interpreter (if required)

Name of interpreter (if present): _____

ID number (if phone interpreter): _____

(The interpreter's name or ID number must be documented in the EMR.)

The participant must be provided with a **signed copy** of this form.

Study Calendar:

This calendar shows the exams, tests, and procedures that will be done as part of this research study, as well as the tests and procedures that are part of your usual care.

	Screening	**Baseline**	**ERT-C or CBT-C sessions**	**After the last ERT-C or CBT-C session (within 1 week)**	**3 months after ERT-C or CBT-C**	**6 months after ERT-C or CBT-C**
Questionnaire	X	X	X	X	X	X
Saliva collection (at home)		X		X (4 times each day for 3 days in a row)	X (4 times each day for 3 days in a row)	X (4 times each day for 3 days in a row)
ERT-C or CBT-C			X (once a week for 8 weeks)			