THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

A randomized controlled trial of eSCCIP: An eHealth psychosocial intervention for English and Spanish speaking parents of children with cancer

2021-0988

Study Chair: Martha A. Askins, 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.

This research has been reviewed and approved by an Institutional Review Board (IRB - a committee that reviews research studies).

STUDY SUMMARY

The goal of this research study is to learn if the Electronic Surviving Cancer Competently Intervention Program (eSCCIP) can help decrease symptoms of distress, anxiety, and stress in parents and caregivers of children with cancer.

The eSCCIP aims to deliver therapeutic content for parents and caregivers of children with cancer through a combination of self-guided interactive online content and telehealth follow-up with a therapist.

This is an investigational study.

Participants may benefit psychologically by learning coping skills and ways to support all family members during this study. The education materials offered in the comparison group may also help you cope and support others. 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

potential expenses and time commitment. Participants may not wish to participate in the study, because thinking about and talking about coping with childhood cancer may feel difficult at times. To take part in this study, you will need to have internet access through an electronic device such as a tablet or computer.

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

Your participation in this study will be over after completing the 3-month follow-up questionnaires.

There will be no cost to you for taking part in this study.

You may choose not to take part in this study.

1. STUDY DETAILS

Up to 420 individual participants (representing 350 families) will be enrolled in this multicenter study. Up to 126 individuals (representing 105 families) will take part at MD Anderson.

If you agree to take part in this study, you will be randomly assigned (as in the flip of a coin) to either the eSCCIP program or an electronic education program. If 2 caregivers from the same family participate, both will be assigned to the same program. This is done because no one knows if one group is better, the same, or worse than the other group.

If you are assigned to the eSCCIP program, you will complete up to 4 online modules (called “Cores”) and 3 telehealth follow-ups over 1 month. Each module will take about 30 minutes to complete:

- Core 1 will help identify and discuss issues and beliefs about cancer and its impact on the family. In Core 1, you will also review the overall module goals and provide the therapist with information about yourself (such as your first name and your child’s first name).
- Core 2 is designed to help recognize and change distressing beliefs that may lead to future problems.
- Core 3 will help you identify and discuss beliefs about the future of the family and help the family imagine a life after cancer treatment ends.
- Core 4 will be a summary of what you learned in the other cores and will provide access to multiple resources that you may access at any time following completion of the program.

Each module is a unique mix of original video content and interactive activities. Cores 1 through 3 are paired with brief telehealth follow-up meetings performed by a counselor. At these follow-ups, you will review the skills you learned and discuss how these can be applied to your own life. If you complete the intervention with a second

parent or caregiver (for example, your spouse), you will have the option of completing the follow-ups individually or together.

Telehealth follow-up meetings will be audio-recorded to help make sure that the meeting leaders are covering all of the important topics planned. 15% of the recordings will be reviewed for this purpose. The audio-recordings will be labeled with the study identification number only and sent via encrypted e-mail to the fidelity consultant at Nemours Children's Health. Recordings will then be transferred to a secure, internal, password-protected electronic drive at Nemours Children's Health. After the audio check is complete, recordings will be deleted from the computer.

The module and follow-ups will be done by 1 or 2 parents and/or caregivers per family, but the module content is made to apply to the whole family.

If you are assigned to the education program, you will be given access to a website with resources about coping with cancer (for example, stress management and recognizing symptoms of traumatic stress). You can look over these materials at any time according to your own schedule.

All participants will complete questionnaires online at 3 time points: at baseline, which is close to the time you sign this consent form and before Core 1; after the final telehealth meeting; and at the three-month follow-up. The questionnaires will ask about topics like your stress levels, mental health, and coping abilities. Questionnaires will take between 20 and 30 minutes to complete. Answers will not be shared with the healthcare team or other caregivers/parents, including the second caregiver from the same family.

2. POSSIBLE RISKS

There is a risk of **emotional discomfort** when completing study questionnaires that ask you about how you are feeling. Similarly, there is a risk of experiencing emotional discomfort while participating in the program, because it will address coping with your child's cancer treatment. You may refuse to answer any question. If you have concerns after completing the questionnaire(s), you are encouraged to contact your doctor or the study chair.

If the study coordinator thinks that you may be experiencing high levels of distress while taking part in the study, they will tell the study doctor. You will then be referred to a licensed social work counselor or psychologist for additional help. If needed, the study doctor will follow up with you at the next scheduled telehealth meeting.

Although every effort will be made to keep study data safe, there is a chance that your information could be lost or stolen, which may result in a **loss of confidentiality**. Researchers will take appropriate steps to keep your information private. However, there is no guarantee of absolute privacy.

This research is covered by a **Certificate of Confidentiality** (CoC) from the National Institutes of Health. The researchers with this CoC may not disclose or use information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information protected by this CoC cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below).

The CoC cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation. You should understand that a CoC does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The CoC will not be used to prevent disclosure for any purpose you have consented to.

This study may involve unpredictable risks to the participants.

OPTIONAL PROCEDURES FOR THE STUDY

You do not have to agree to the optional procedure in order to take part in this study. There are no benefits to you for taking part in the optional procedure. Future patients may benefit from what is learned. You may stop taking part at any time. There will be no cost to you for taking part in the optional procedure.

Optional Procedure #1: If you agree, you will take part in an interview to learn more about your experience with eSCCIP, including how the strategies learned through the modules were used and possible costs and savings of using a program like eSCCIP. You will complete the interview via phone or in person sometime after completing the 3-month follow-up surveys. The interview will be audio-recorded and transcribed (written down) for research purposes. No identifying participant names will be included. Once the audio recordings have been transcribed and identifying information is removed, the recording will be deleted. The interview is expected to take about 45 minutes.

One parent or caregiver can choose to participate in the interview, even if the second parent chooses not to participate. Parents/caregivers will be interviewed individually. Please note, if you agree to the interview, you may or may not be contacted, depending on when enough interviews have been completed to meet study goals.

At the end of the interview, you will receive a $30 gift card.

Optional Procedure Risks

There is a risk of **emotional discomfort** when completing the optional interview. You may refuse to answer any question. If you have concerns after completing the interview, you are encouraged to contact your doctor or the study chair.

Researchers will take appropriate steps to keep your information private. However, there is no guarantee of absolute privacy.

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

Circle your choice of "yes" or "no" for each of the following optional procedures:

Optional Procedure #1: Do you agree to take part in the interview so that researchers can learn more about your experience with eSCCIP?

YES **NO**

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 or National Institute of Health 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.

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

You will receive a $30 reloadable gift card once you complete the questionnaire after your last telehealth meeting. An additional $10 will be added to the gift card after you complete the 3-month follow-up questionnaires.

Additional Information

4. You may ask the study chair (Dr. Martha Askins, at 713-794-4467) 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 decide you want to stop taking part in this study, tell the study chair. If you withdraw from this study, you can still choose to be treated at MD Anderson.

   If you stop being in the research, already collected data may not be removed from the study database.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, National Institute of Health, 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.

9. This study is sponsored and/or supported by: National Institute of Health.

10. In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s)/supporter. If you have any questions about this, you may call the IRB at 713-792-6477.

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 National Institute of Health and/or shared with other researchers and/or institutions for use in future research.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or shared with another researcher for future research studies without your additional informed consent.

In some cases, all of your identifying information may not be removed before your data or research samples 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 and/or samples.

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
   - National Institute of Health (NIH), who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study
   - Limited data will be shared with researchers at Nemours Center for Healthcare Delivery Science, the University of Southern California/Children's Hospital of Los Angeles, and the University of Virginia, , for the purpose of reviewing participant understanding of the electronic intervention (applicable to Nemours Center, University of Southern California/Children's Hospital of Los Angeles, and MD Anderson Cancer Center) and program maintenance (applicable only to UVA).
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

   The results of this research may be published in professional journals or presented at meetings. Any personal identifying information will not be included in these presentations or publications.

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

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under this protocol.

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

A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

_____
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.)