Title of Study: Acceptability and Feasibility of a Brief Psychoeducational Intervention for Parents of Children With Childhood Cancer

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The University of New Mexico Health Sciences Center
Consent to Participate in Research

Learning and Education in Childhood Cancer
Version date: 12/8/2021

Introduction
You are being asked to participate in a research study that is being conducted by Eric Zimak, Ph.D., ABPP-CN who is the Principal Investigator. Dr. Zimak (from the Department of Psychiatry and Behavioral Sciences) is working along with collaborators in the Department of Pediatric Hematology/Oncology at UNMH and a collaborator at Cure 4 The Kids. This research is studying the feasibility and acceptability of a brief intervention on learning and education in children currently undergoing treatment for cancer or who recently completed treatment.

You are being asked to participate in this study because you and your child meet the following eligibility criterion:

- Your child has a cancer diagnosis and is currently undergoing treatment at University of New Mexico (UNM) Hospital or recently completed treatment.
- Your child is currently between 3 and 14 years of age (or was 14 at the time of the screening).
- Your child currently lives in New Mexico.
- You, the parent/legal guardian, are willing to complete forms offering information about your child and your family.
- Your preferred language for oral and written communication is English.
- You are 18 years of age or older.

UNM Health Sciences Center is the only study site for data collection. The intervention may take place on a HIPAA compliant Zoom format at UNM Health Sciences Center or at another location. We ask you complete the study in a private space, with only individuals present who are participating in the study. Also, please identify your child's name and date of birth verbally.

This form will explain the research study and will explain the possible risks and benefits. We encourage you to talk with your family and friends before you decide to take part in this research study. If you have any questions, please ask one of the study investigators.

Note that each parent/guardian will be treated as a separate participant, which includes completing separate consent forms. When two parents/guardians participate in the study intervention, they will have separate, but linked ID numbers to identify that they are providing information about the same child. In this case, one participant will be identified as primary, given some questionnaires will only be completed by one of the participants.

What will happen if I decide to participate?
If you agree to participate, the following things will happen:

- You, the parent or legal guardian, will be asked to answer questions about your experiences and thoughts about your child's cancer, treatment, and functioning. You will also be asked to provide additional information about your child, his/her caregivers, and his/her family.
- You, the parent or legal guardian, will be asked to participate in a program discussing your child's learning, education, and psychosocial functioning.
- You, the parent or legal guardian, will be asked to complete a program evaluation form.
- Participation in this study does not involve drugs or medical devices.

HIPAA Authorization for Use of Your Protected Health Information (HIPAA)

As part of this study, we will be collecting health information about you and your child. This information is "protected" because it is identifiable or "linked" to you and your child.

Protected Health Information (PHI)

By signing this Consent Document, you are allowing the investigators and other authorized personnel to access your child's UNM medical record. This will allow study investigators to access data about your child's medical history, such as the type of cancer diagnosis, date of diagnosis, and treatments received.

You are under no obligation to agree to have this data accessed. You can continue to participate in this study even if you decline to have your child's UNM medical record accessed. Please identify whether you give us consent to access your child's medical record below.

_____ Yes, I consent for study personnel to access my child's UNM medical record.

_____ No, I do not consent for study personnel to access my child's UNM medical record.

How long will I be in this study?

Participation in this study will take a total of approximately 2 hours over a period of one day (Note: It is likely this study will take 30 to 45 minutes longer if two individuals are completing forms on a single electronic device). You will receive a brief debriefing of the study after the visit.

What are the risks or side effects of being in this study?

There are risks of possible loss of privacy and confidentiality associated with participating in a research study and in participating in a research study via technology. These risks are thought to be low. Study personnel will take actions to minimize loss of privacy as much as possible. To minimize this risk, all data is de-identified, meaning that your name is not listed on data forms. Electronic data will ultimately be stored in password protected files on secured drives. Physical data will ultimately be stored in locked cabinets at the UNM Center for Neuropsychological Services. Discussion of sensitive issues, such as cancer, cancer treatment, and potential cognitive, psychological, and educational effects, may result in distress for some participants. If you experience psychological distress as a result of study participation, please discuss this with study personnel. Methods for accessing resources to

mental health services will be provided upon debriefing; please contact the study's primary investigator, Eric Zimak, Ph.D., ABPP-CN at 505-272-8833, should you have any additional questions.

For more information about potential risks, ask the investigator.

What are the benefits to being in this study?

You will receive information regarding cognitive and psychological late effects, school supports and resources, and neuropsychological and school evaluations. The information in this program will be provided in both oral and written forms. This information may be helpful for parents to assist with their child's learning and development over time.

What other choices do I have if I do not want to be in this study?

This is a voluntary study and you can withdraw from study participation at any time. Choosing to withdraw participation will not affect the healthcare that you receive. If you wish to have your study data destroyed, you must write a letter to Dr. Zimak to request that your data is destroyed. Upon receipt of this written request, all of your data that was collected for this study will be deleted from electronic files and paper documents will be shredded. Once this is performed, you may not re-enroll in the study.

How will my information be kept confidential?

We will take measures to protect the security of all your personal information, but we cannot guarantee confidentiality of all study data. To help ensure confidentiality, each participant will be assigned a study ID number that will be stripped of any personal identifying information.

The link between the study ID and personal identifying information will be kept, separate from study data, in a password protected file on a secured drive accessible only to study personnel. Electronic data will be stored on a secure database (REDCap) and ultimately be stored in password protected database files on secured drives with access limited to research personnel and the REDCap system administrator. Technical professionals involved with REDCap may also have some access to the REDCap system.

Hardcopy paper data will ultimately be kept in a locked file cabinet in an office within the University of New Mexico, Health Sciences Center. We will also make audio recordings to ensure that we are following the research protocol; these recordings will also ultimately be kept in a locked file cabinet and destroyed when they are no longer needed to determine whether the research protocol was followed. Note that we will keep data from our participants until the last participant's child reaches 22 years of age. Your name and your child's name will <u>not</u> be used in any published reports about this study.

Information contained in your study records is used by study staff. The University of New Mexico Health Sciences Center Human Research Review Committee (HRRC) that oversees human subject research, and

the Food and Drug Administration and/or other entities may be permitted to access your records. There may be times when we are required by law to share your information. In addition to researchers and staff at UNMHSC and other groups listed in this form, there is a chance that your health information may be shared (re-disclosed) outside of the research study and no longer be protected by federal privacy laws. Examples of this include disclosures for law enforcement, judicial proceeding, health oversight activities and public health measures.

What are the costs of taking part in this study?
There are no direct costs to the participants or their third party payer for study participation.

What will happen if I am injured or become sick because I took part in this study?
If you are injured or become sick as a result of this study, UNMHSC will provide you with emergency treatment, at your cost. No commitment is made by the University of New Mexico Health Sciences Center (UNMHSC) to provide free medical care or money for injuries to participants in this study.

In the event that you have an injury or illness that is caused by your participation in this study, reimbursement for all related costs of care will be sought from your insurer, managed care plan, or other benefits program. If you do not have insurance, you may be responsible for these costs. You will also be responsible for any associated co-payments or deductibles required by your insurance.

It is important for you to tell the investigator immediately if you have been injured or become sick because of taking part in this study. If you have any questions about these issues, or believe that you have been treated carelessly in the study, please contact the Human Research Review Committee (HRRC) at the University of New Mexico Health Sciences Center, Albuquerque, New Mexico 87131, (505) 272-1129 for more information.

Will I be paid for taking part in this study?
Because the study requires approximately two hours of your time, each participant will be reimbursed with a $40 merchandise card at the completion of this study. This merchandise card may be provided to the participants at UNMH or mailed to the participant(s) after study completion. If the merchandise card is mailed to the participant(s), the information below may be retrieved over the phone with documentation that the visit was conducted remotely and the card was sent to the participant(s). The participant will be asked to confirm an address at the end of the study session if s/he wants the merchandise card mailed.

If you receive more than the minimum reporting requirements as set by the Internal Revenue Service (>$599 in a calendar year), the University of New Mexico must report this income to the IRS and will issue you a 1099 form. We will ask that you provide your social security number, and your contact information including your address, phone number and e-mail address for this purpose. You will be responsible for reporting this compensation when you file your tax return.

How will I know if you learn something new that may change my mind about participating?

You will be informed of any significant new findings that become available during the course of the study, such as changes in the risks or benefits resulting from participating in the research or new alternatives to participation that might change your mind about participating.

Can I stop being in the study once I begin?
Your participation in this study is completely voluntary. You have the right to choose not to participate or to withdraw your participation at any point in this study without affecting your future health care or other services to which you are entitled.

You may withdraw from the study after your data is collected. If you would like to withdraw from the study and have your data destroyed, you must write to the primary investigator and request that your data is destroyed. Once the request is received, all data that was collected for you for this study will be deleted from electronic files and paper documents will be shredded.

If it is determined that you are unable to consent, the primary investigator may choose to withdraw study participation. If this occurs, the participant will be offered a $40 merchandise card reimbursement for your time.

What other information is helpful to know?
Hyundai Motor America (Hope on Wheels) provided financial support and/or material for this study.

A description of this clinical trial will be available on ClinicalTrials.gov. 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.

Whom can I call with questions or complaints about this study?
If you have any questions, concerns, or complaints at any time about the research study, please contact Eric Zimak, Ph.D., ABPP-CN at 505-272-8833. Dr. Zimak and/or his associates will be glad to answer your questions. If you need to contact someone after business hours or on weekends, please call 505-272-8833 and leave a voicemail; barring unforeseen circumstances, your call will be returned within two days. If you experience an emergency at any time, call 911. If you would like to speak with someone other than the research team, you may call the UNMHSC HRRC at (505) 272-1129.

Whom can I call with questions about my rights as a research participant?
If you have questions regarding your rights as a research participant, you may call the UNMHSC HRRC at (505) 272-1129. The HRRC is a group of people from UNM and the community who provide independent oversight of safety and ethical issues related to research involving human participants. For more information, you may also access the HRRC website at https://hsc.unm.edu/research/hrpo/.

CONSENT

You are making a decision for you to participate in this study. Your signature below indicates that you have read the information provided or the information was read to you. By signing this consent form, you are not waiving any of your legal rights as a research participant.

I have had an opportunity to ask questions and all questions have been answered to my satisfaction. By signing this consent form, I agree to participate in this study. A copy of this consent form will be provided to you.

_____

Name of Parent/Child's Legal Guardian (Print)

_____ _____

Signature of Parent/Child's Legal Guardian Date

INVESTIGATOR SIGNATURE

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information described in this consent form and freely consents to participate.

_____

Name of Investigator/ Research Team Member (Print)

_____ _____

Signature of Investigator/ Research Team Member Date