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Feasibility of Expressive Writing for Body Image Distress and Anxiety Among Adolescent and Young Adult Cancer Survivors

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Determining the Feasibility of Expressive Writing for Body Image Distress and Anxiety Among Adolescent and Young Adult Cancer Survivors

Company or agency sponsoring the study: The study is supported by the 2024 CONQUER CANCER – ANNA BRAGLIA ENDOWED YOUNG INVESTIGATOR AWARD IN CANCER SUPPORTIVE CARE.

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):

Principal Investigator: Victoria Wytiaz, MD; University of Michigan, Department of Hematology/Oncology

1.1 Key Study Information

You, or your child, may be eligible to take part in a research study. Parents or legal guardians who are giving permission for a child's participation in the research, note that in the sections that follow the word 'you' refers to 'your child'. This form contains information that will help you decide whether to join the study. All of the information in this form is important. Take time to carefully review this information. After you finish, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your friends, family, or other doctors about your possible participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you do, be sure you understand what the study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research is studying whether an at-home, body-image focused expressive writing intervention is a feasible intervention for addressing body image distress and anxiety in adolescent and young adult (AYA) cancer survivors. This research will explore the impact of a four week, at-home, body-image focused expressive writing intervention on body image distress and anxiety among AYA cancer survivors with clinically relevant body image distress and anxiety. You will be randomly assigned to a four week, at-home, body-image focused expressive writing intervention or a four week, at-home, control writing group.

Your health-related information, such as body image distress or anxiety severity, will be collected for this research study at baseline, and four weeks.

This study involves a process called randomization. This means that the intervention you receive in the study is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a coin), to compare different treatments or procedures. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include distress related to answering survey questions or participating in one of the treatment conditions and the potential for loss of confidentiality or privacy. More detailed information will be provided later in this document.

This study may offer some benefit to you now or others in the future by improving cancer treatment-related symptom severity, such as body image distress or anxiety. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be one month.

You can decide not to be in this study. Alternatives to joining this study include deciding not to participate in this research or participating in another research study.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

60% of adolescent and young adults (AYAs) with cancer experience body image distress (BI). Body image is developed in adolescence and young adulthood and affects self-identity and quality of life. Cancer itself and cancer treatments can change appearances as well as body sensation and function, all of which can alter BI and lead to increased anxiety. BI distress is not well-managed due to multiple factors, including lack of time and lack of provider expertise. BI distress experienced by people with eating disorders or body dysmorphic disorders is usually treated with medications or psychotherapy. However, there are no treatments to help AYA cancer survivors cope with BI distress that is not associated with an eating disorder or body dysmorphic disorder diagnosis. To address the lack of treatments available for cancer survivors with BI distress, the goal of this study is to implement a four-week BI-focused expressive writing (EW) program and to assess its impact on BI distress and anxiety among AYA cancer survivors. An in-home BI-focused EW program offers a promising solution for addressing BI distress and anxiety as expressive writing is self-directed by the patient. EW may help improve quality of life in adult cancer patients. Pediatric cancer patients may have better emotional regulation and school performance with age-adapted EW interventions.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

You are invited to take part in this research study because you are a 15 – 39-year-old individual with a history of one or more cancer diagnoses within the past 5 years and with all treatment (surgery, chemotherapy, radiation) completed ≥ 3 months ago. You must also report clinically relevant body image distress in the past seven days. You are not eligible to take part in this study if you plan to begin cancer treatment during the study period, have initiated new treatments for body image distress or anxiety (e.g., pharmacologic, psychotherapy) ≤8 weeks prior to study enrollment, have a history of limb-altering surgery or amputation, or are receiving end of life care.

3.2 How many people are expected to take part in this study?

It is expected that 30 participants will participate in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Before the research starts, you will be asked to undergo some screening tests to find out if you can be in the research study. Mainly, we will ask you questions about your medical history, which includes questions about your health, current medications, cancer history, and body image distress and anxiety severity.

If these screening questions show that you are eligible to participate in the research study and you agree to participate, you will be randomized (e.g., flip of a coin) to one of two treatment conditions.

Body Image Focused Expressive Writing Intervention

If you are randomized to the body image focused expressive writing intervention, you will participate in four weekly writing sessions (four weeks total) of 20 minutes duration. Participants in this group will be contacted via email weekly with the writing assignment/prompt and instructions to complete a 20-minute in-home writing session. Email prompts will also encourage patients to set a timer for 20 minutes prior to writing initiation. The intervention writing program will include four prompts that probe participants' thoughts and feelings regarding body image and the cancer experience. Finally, following the study period, you will complete questionaries to assess body image distress and anxiety severity and you will have the opportunity to participate in a semi-structured interview to discuss your perspectives of the intervention. All interviews will be conducted either in person or using telephone or Zoom and will be audio recorded.

Control

If you are randomized to the control condition, you will participate in four weekly writing sessions (four weeks total) of 20 minutes duration. Participants in this group will be contacted via email weekly with the writing assignment/prompt and instructions to complete a 20-minute in-home writing session. Email prompts will also encourage patients to set a timer for 20 minutes prior to writing initiation. The control writing program will include four prompts regarding neutral topics unrelated to the cancer experience. Finally, following the study period, you will complete questionaries to assess body image distress and anxiety severity and you will have the opportunity to participate in a semi-structured interview to discuss your perspectives of the intervention. All interviews will be conducted either in person or using telephone or Zoom and will be audio recorded.

Data Collection

Regardless of treatment assignment, participants will complete electronic surveys about body image distress, anxiety, and demographics. A study team member will call you to review your use of medications or treatments for anxiety or depression at baseline and at the end of the study. Following the study period, a study staff member will abstract information about your cancer treatment history from the medical record.

As a subject participating in this research study, you have certain responsibilities that may apply to this study, such as ensuring that you arrive at all of your scheduled appointments, take your study medication as directed, and report any adverse reactions you may have during the study.

4.2 How much of my time will be needed to take part in this study?

You will be in the study for approximately one month. Expressive writing group participants and control group participants will receive writing prompts weekly for four weeks (20 minutes per week). Participants will also have the opportunity to participate in an interview at the end of the study (approximately 45-60 minutes). All participants will complete surveys at two time points, the beginning of the study and at the conclusion of the intervention/time of semi-structured interview. it is expected that the surveys will take approximately 25-40 minutes to complete at each time point.

4.3 When will my participation in the study be over?
Your participation in the study will be over after you complete the four-week study period and surveys/interviews. In addition, a study staff member will abstract information from your medical record shortly after you complete the study.

4.4 What will happen with my information and/or biospecimens used in this study?
With appropriate permissions, your biospecimens and collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

- Anxiety/distress related to reading or answering the survey questions
- Anxiety/distress related to participating in the expressive writing intervention

The researchers will try to minimize these risks by:

- To decrease the risk of increased anxiety/distress when answering survey questions or participating in the expressive writing intervention, we will refer any participants experiencing anxiety or distress to their usual care provider. In addition, participants will be encouraged to not engage in any activities that make them uncomfortable.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors.

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

Possible benefits of the research for society include the identification of a promising non-medicine treatment for body image distress and anxiety among adolescent and young adult cancer survivors. Future studies may be conducted to determine if the body image focused expressive writing intervention truly works to improve body image distress and anxiety. However, some subjects may experience improvements in cancer treatment-related symptoms following participation in the intervention.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

Participation in this study is voluntary. You do not have to agree to be in this research study. You have other options such as deciding not to participate in this research study or participating in another research study.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information".

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
Participation in this study is voluntary. There are no penalties to you for not participating in this study or leaving the study early. You can choose to stop participating in the research study at any time. Tell the investigator or a research staff member if you are thinking about stopping or decide to stop. He or she will tell you how to stop. Leaving the research study will not affect your medical care outside of the research study.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

There are no costs or billing for this study.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

You will receive a $50 gift card if you participate in one of the treatment conditions and complete the required surveys.

8.3 Who could profit or financially benefit from the study results?

No person or organization has a financial interest in the outcome of the study.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

We will take several steps to decrease the risk of loss of privacy and confidentiality.

- All written study materials will be numbered with participant ID numbers and not participants' actual names.
- Paper/pencil data collection forms and informed consent documents will be stored in locked cabinets at the University of Michigan.
- All collected patient-reported outcomes will be directly entered into secure online databases.
- Only the research team and your clinicians will be able to see the information you report.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Mental health care records (except psychotherapy notes not kept with your medical records)
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Victoria Wytiaz
Mailing Address: Division of Hematology/Oncology, 1500 E Medical Center Drive, Ann Arbor, Michigan 48109-5848
[redacted]

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
[redacted]

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?
Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*
- A copy of the signed and dated informed consent

12. SIGNATURES

Sig-A

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-B

Consent/Assent to video/audio recording/photography solely for purposes of this research
This study involves video and/or audio recording and/or photography. If you do not agree to be recorded, you CAN STILL take part in the study.

_____ Yes, I agree to be video/audio recorded/photographed.

_____ No, I do not agree to be video/audio recorded/photographed.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-E

Legally Authorized Representative or Parent Permission

Subject Name:

_____

Parent/Legally Authorized Representative:

Printed Legal Name:

_____

Signature: _____

Address: _____

Date of Signature (mm/dd/yy): _____

Relationship to subject: ☐ Parent ☐ Spouse ☐ Child ☐ Sibling ☐ Legal guardian ☐ Other

If "Other," explain: _____

Reason subject is unable to consent: _____

If this consent is for a child who is a ward of the state (for example, a foster child), please tell the study team immediately. The researchers may need to contact IRBMED.

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____