Official Title: Post-chemotherapy Symptom Management: Testing Intervention Sequences in a SMART Design

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THE UNIVERSITY OF ARIZONA College of Nursing

Consent to Participate in Research

Study Title: Post-chemotherapy Symptom Management: Testing Intervention Sequences in a SMART Design

Principal Investigator: Terry Badger, PhD, RN, Alla Sikorskii, PhD

Sponsors: National Cancer Institute
University of Arizona Cancer Center

Summary of the Research

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

You are being asked to participate because you have been diagnosed with a solid tumor cancer and are completing or have completed chemotherapy. This study is about learning how to manage symptoms you experienced during treatment, symptoms that may linger post-treatment, and what to do after the end of chemotherapy to improve your health and prevent cancer from coming back. This study will take 13 weeks. You will be called to complete all study questionnaires twice, and every week for 12 weeks someone will call you to discuss your symptoms and well-being. There is minimal risk to you and you may benefit from learning more about how to manage your symptoms, including psychological distress.

The University receives compensation from the sponsors of this study for the conduct of this study. If you have any questions, please discuss this with your doctor.

Why is this study being done?

You are being invited to participate in this research study to determine the potential benefits of two therapies designed to relieve symptoms that persist after completion of chemotherapy. The purpose is to learn if either of the two therapies, a printed Symptom Management and Survivorship Handbook or Telephone Education and Counseling Intervention will help you feel better physically and/or emotionally following cancer treatment. We will also ask for your permission to collect Protected Health Information (PHI) for this study to help the researchers answer the questions asked in this research study.

What will happen if I take part in this study?

This study will take 13 weeks. If you consent to participate you will be called to complete all study questionnaires twice, and every week for 12 weeks someone will call you to discuss your symptoms and well-being. You will be called via the telephone at a time convenient for you to collect information on your well-being, any illnesses you have, and symptoms you experience. The call will take 30-40 minutes to complete. Another 30-40-minute call will be made at week

13 to collect information on any changes in your well-being and symptoms. All calls will be made at times that are convenient to you.

Information from the first call will be used to determine whether you will be randomized to study interventions, or will be in a follow-up group that will receive the 13-week call described above and a brief call at week 4 to assess your symptoms. Approximately 35% of all participants will be in this follow-up group (**Group C**).

If based on the first call you are determined to be eligible for study interventions, you will be randomly assigned to one of two groups, A or B, using a procedure which is "like with a flip of a coin". At this point, the chance of being randomized to Group A is about 77%, to Group B is about 23%.

Group A: If you are in Group A, we will mail you the printed Symptom Management and Survivorship Handbook, in either English or in Spanish (your preferred language) after the first assessment. You will be called every week for 4 weeks to ask about your symptoms and suggest that you use strategies from the printed Handbook to help relieve symptoms or answer questions about survivorship care that you may have. These calls will take place when it is convenient for you and will last approximately 10 minutes.

After the first four weeks of receiving the telephone calls assessing your symptoms and directing you to the printed materials, you may continue to receive these brief calls for additional 8 weeks. It is also possible that after the initial 4 weeks you will be randomly assigned to additionally receive Telephone Education and Counseling Intervention for the subsequent 8 weeks. The counselor will call you once per week for about 35-40 minutes to assess and discuss strategies for the management of your symptoms, provide cancer survivorship education, and discuss interpersonal relationships, communication, and social support. At week 13, you will receive a final 30-40-minute call where we will ask about your well-being and symptoms.

Group B: If after the initial assessment you are randomized to Group B, we will mail you the printed Symptom Management and Survivorship Handbook, in either English or in Spanish (your preferred language). In addition, you will also receive the telephone education and counseling intervention. During the first 8 weeks, the counselor will call you once per week for about 35-40 minutes to assess and discuss strategies for the management of your symptoms, provide cancer survivorship education, and discuss interpersonal relationships, communication, and social support. The final 4 weeks will involve briefer 10-minute telephone calls to ask about your symptoms and suggest that you use strategies from the printed Handbook. At week 13, you will receive a final 30-minute call where we will ask about your well-being and symptoms.

Will video or audio or text recordings be made of me during the study? Yes, we will make an audio or text recording of your sessions for quality control purposes to make sure that the counselors are following the protocol ***only*** if you check the box below:

☐ I give my permission for audio or text recordings to be made of me during my participation in this research study. All communications (assessments, intervention sessions, text messages to remind me of appointments, my texts to the counselor) will be recorded.

☐ I do not give my permission for audio or text recordings to be made of me during my participation in this research study.

How long will I be in this study?
Your total participation in the study will not exceed 13 weeks.

How many people will take part in this study?
Approximately 600 cancer survivors will take part in this study.

What risks, side effects or discomforts can I expect from being in the study?
Your participation in this study is voluntary. There are minimal risks to participating in this research. Discussions about how you cope with your symptoms post-chemotherapy over the telephone may make you uncomfortable, and you can stop at any time. You can also ask for a referral to the appropriate social service agency or provider. There are no documented risks associated with the interventions offered in this study.

What benefits can I expect from being in this study?
The potential benefits to participating in the study are that participants who participate in the interventions may experience an improved symptom resolution following the end of chemotherapy. Given the ability to access the interventions by telephone, cancer survivors may receive treatment for which they normally would not be able to access. Spanish speaking participants and rural dwellers do not have access to the same level of services that urban dwellers and English-speaking participants do. Further, participation in this study may help future cancer survivors by providing information that can be used to develop effective and accessible supportive care after the end of chemotherapy. Another potential benefit and knowledge gained would involve identifying the individuals who benefit from this kind of approach so that in the future such treatments can be prescribed. Therefore, the Risk/Benefit ratio is heavily weighted in favor of benefit.

What happens if I am injured because I took part in this study?
Side effects (injury) can happen in any research study. These effects may not be your fault or the fault of the researcher involved. Known side effects have been described in the "What risks, side effects or discomforts can I expect from being in the study?" section of this consent form. There are minimal risks to this study. In the unlikely event, you suffer an injury from participating in this study, you should seek treatment from your own health care provider or go to your local Emergency Department. This, however, does not waive your rights in the event of negligence. If you suffer an injury from participating in this study, you should seek treatment. The University

of Arizona and Banner University Medical Group have no funds set aside for the payment of treatment expenses for this study.

What other choices do I have if I do not take part in the study?
Your participation is voluntary. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The University of Arizona or Banner Health. If you are a student or employee at the University of Arizona, your decision will not affect your grades or employment status.

When may participation in the study be stopped?
You may choose not to participate in this study without affecting the healthcare you receive, without penalty or loss of benefits to which you are otherwise entitled. You may simply tell us that you wish to stop the study and we will no longer contact you. You may ask questions about this research at any time. Your participation maybe stopped by the study clinician or study sponsor, without your consent, but the reasons will be explained to you. You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

What are the costs of taking part in this study?
The services performed for this research will be provided to you at no charge. There are no costs to be in this study except for your time. The total time involved will be between 2 to 6 hours depending on which group you are assigned.

Will I be paid for taking part in this study?
Compensation for participation in a research study is considered taxable income for you. We are required to obtain your name, address, and Social Security number for federal tax reporting purposes. If your compensation for this research study or a combination of research studies is $600 or more in a calendar year (January to December), you will receive an IRS Form 1099 to report on your taxes. For this study, you will receive a $40 gift card from a local retail merchant and thank you letter after the first assessment, which is before the 12 week intervention period in Groups A and B, and a $50 gift card and thank you letter after the second assessment during week 13. You will receive a total of $90 in gift cards for completing these two assessments regardless of which group (A, B, C) you were in.

Will my study-related information (data) be used for future research?
All data collected will be stored for future analysis. Information collected from you may be used for future research or shared with another researcher for future research studies without additional consent. Your information will not be identified with you.

Will I hear back on any results that directly impact me?
If we write a report or article about this research study, we will describe the research study results in a way that you cannot be identified. During the course of the research study, you will

be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from taking part in the research or new alternatives to participation that might cause you to change your mind about continuing in the study.

Will my study-related information be shared, disclosed, and kept confidential?
Every effort will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

To help us protect your privacy, we have obtained a Certificate of Confidentiality (CoC) issued by the National Institutes of Health (NIH). The CoC is issued to protect the investigators on this study from being forced to tell anyone about your participation in this study, even under a subpoena. The information will be used by the sponsor, the University, and regulatory agencies that support or oversee the research.

Even when a CoC is in place, you and your family members must continue to actively protect your own privacy. If you voluntarily give your written consent for an insurer, employer, or lawyer to receive information about your participation in the research, then we may not use the CoC to withhold this information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities for reporting of child abuse or neglect, or as required by law to prevent harm to self or others.

It is anticipated that there will be circumstances where your study related information and PHI will be released to persons and organizations described in this form. If you sign this form, you give permission to the research team to use and/or disclose your PHI for this study. Your information may be shared or disclosed with others to conduct the study, for regulatory purposes, and to help ensure that the study has been done correctly. These other groups include:

- Office for Human Research Protections or other federal, state, or international regulatory agencies
- Banner University Medical Group and Banner Health
- The University of Arizona (UA) and the UA Institutional Review Board
- Michigan State University (MSU) and the MSU Institutional Review Board
- Cancer Support Community Arizona
- The sponsor supporting the study, their agents or study monitors

Your PHI may no longer be protected under the HIPAA privacy rule once it is disclosed by the research team.

What study-related information and PHI will be obtained, used or disclosed from my medical record at Banner?
Information related to this research study that identifies you and your PHI will be collected from your past, present, and future hospital and/or other health care provider medical records.

The PHI you are authorizing to be used and/or disclosed in connection with this research study is: Your cancer site and stage of cancer, the treatments that you have received for your cancer, any symptoms you may have experienced from your treatments and any other illnesses that you may have in addition to your cancer, and any medications corresponding to your time on study.

Demographic information which you have provided the research staff may include, but is not limited to, your name, address, phone number, or social security number. If you receive compensation for participating in this research study, information identifying you may be used or disclosed as necessary to provide that compensation.

Your existing health records may include information related to the diagnosis or treatment of sexually transmitted disease (STD), acquired immunodeficiency syndrome (AIDS), human immunodeficiency virus (HIV), other communicable diseases, genetic information (e.g., genetic testing), and/or alcohol and/or drug abuse. The study staff and study sponsor's monitor may see this information while reviewing your regular health records for this study, but they WILL NOT create, collect, or disclose this type of information for the purposes of this research study.

When will my authorization expire?
This authorization expires at the end of the research study unless you cancel this authorization (as instructed below) this authorization will continue to be effective.

Do I have to sign this authorization form?
You do not have to sign this authorization. However, if you decide not to sign, you will not be able to participate in this research study; and it will not affect any non-study Banner Health medical treatment or health care, payment, enrollment in any health plans, or benefits.

Also, by signing this form you are authorizing and permitting uses and/or disclosures of your PHI for future research purposes (e.g., informing you of future studies).

You have the choice to indicate whether you would like to be contacted to participate in future research studies. Please mark your selection below:

_____ YES, I may be contacted to participate in future research studies

_____ NO, I may not be contacted to participate in future research studies

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What do I need to know if I decide to cancel my authorization?
After signing the authorization, you may decide to cancel your previous authorization for the research team to use your PHI. If you cancel the authorization, you will no longer be able to stay in the research study. Please note that any PHI collected before you cancel the authorization may still be used. You may revoke the authorization by contacting the Principal Investigator in writing. Contact information is under "Who can answer my questions about the study" at the end of this document.

Will access be limited to your research study record during this study?
You may not have access to the research information developed as part of this study until it is completed.

Who can answer my questions about this study?
If at any time you feel you have had a research-related injury, or for questions, concerns, or complaints about the study you may contact Terry Badger, PhD, RN, PMHCNS-BC at 520-626-6058 or tbadger@email.arizona.edu.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Protection Program at 520-626-8630 orhttp://research.arizona.edu/compliance/human-subjects-protection-program..

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Terry Badger, PhD, RN, PMHCNS-BC at 520-626-6058 or tbadger@email.arizona.edu.

If you have any questions or concerns about the authorization for access to your PHI, you should contact Sue Colvin, Banner Research Regulatory Affairs Director, at (602) 839-4583 or sue.colvin@bannerhealth.com. You may also request and will be provided a copy of the Notice of Privacy Practices.
To cancel your authorization for access to PHI you must notify the *Principal Investigator/Research Team* in writing at the following address:

Terry Badger, PhD, RN, PMHCNS-BC
Professor, College of Nursing
The University of Arizona
1305 N. Martin Avenue
Tucson, AZ 85721

An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

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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.

Signing the consent form

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study and I authorize the use and/or disclosure of my PHI. I am not giving up any legal rights by signing this form. I will be given a signed copy of this form**.**

Printed name of subject	**Signature of subject**	**Date**

Investigator/Research Staff

I have explained the research to the participant or the participant's representative before requesting the signature(s) above. There are no blanks in this document. A signed copy of this form has been given to the participant or to the participant's representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**	**Date**