

Title: SHARE-S Aim 3: Shared Healthcare Actions & Reflections Electronic Systems in Survivorship

NCT04337203

Date: 11/17/21

SHARE-S: SHARED HEALTHCARE ACTIONS & REFLECTIONS

ELECTRONIC SYSTEMS IN SURVIVORSHIP

Informed Consent Form to Participate in Research

Stephanie Sohl, PhD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to pilot and evaluate your feedback on the SHARE-S coaching and texting support program. SHARE-S stands for Shared Healthcare Actions & Reflections Electronic systems in Survivorship. You are invited to be in this study because you are a patient with a survivorship visit scheduled with Wake Forest Baptist Health. Your participation in this research will last about 8-10 weeks.

Participation in this study will involve completing 2 study questionnaires, 3 telephone coaching calls (30-60 minutes each) and 6 weeks of daily text messages (some request responses). You may also be asked to participate in an interview at the end of the study. All research studies involve some risks. A risk to this study that you should be aware of is some emotional discomfort since you will be thinking about and discussing your health. There is also a slight risk of a potential breach of confidentiality. There is also the possibility that you may benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. Your alternative is to not participate in this study. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Stephanie Sohl, PhD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: [REDACTED].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [REDACTED] or the Research Subject Advocate at Wake Forest at [REDACTED].

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you are a patient receiving cancer survivorship care at Wake Forest Baptist Health. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any

Page 1 of 7
Adult Consent Form

words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to pilot and evaluate your feedback on the SHARE-S coaching and texting support program.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Approximately 40 people will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

Once you agree to participate and are enrolled, we will ask you to complete two study questionnaires, one at the beginning and one at the end of the study. The questionnaires ask for basic information about you, your health, emotional functioning, and symptoms. Each questionnaire will take approximately 30 minutes or less to complete and will not require any additional clinic visits.

We will then invite you to talk on the phone or via videoconference with a health coach about selecting personalized health goals three times to support your survivorship visit. The first will be scheduled after agreeing to participate in the study and the second two will be spaced approximately 3 weeks apart. You will also receive 3 weeks of daily text messages/emails in between the coaching calls (for a total of 6 weeks) to enhance your goal setting experience. Some of these messages will ask you for a brief response.

You may be asked to complete an interview at the end of the study either in person or by telephone.

As part of this research study, we request that you be audiotaped during the coach calls and follow-up interview. This is being done for quality assurance and to gather feedback about your experience with the program. You may request the recording be stopped at any time during the course of the research study. You can also withdraw your consent to use and disclose the audiotape before it is used. You should also understand that you will not be able to inspect, review, or approve the audiotapes or other media (including articles containing such) before they are used in this study.

Please choose one of the following regarding the use and disclosure of the audiotape used in this research study:

I would like the audiotapes of me to be destroyed once their use in this study is finished.

The audiotapes of me can be kept for use in future studies provided they are kept secure and any future study will be reviewed by an IRB. I understand that I will not be able to inspect, review or approve their future use.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 8-10 weeks.

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first.

WHAT ARE THE RISKS OF THE STUDY?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There may be other risks of participating that we cannot predict.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be: a personalized health plan and potential increase in motivation for improving your health.

WHAT OTHER CHOICES ARE THERE?

This is not a treatment study. Your alternative is to not participate in this study.

WHAT ARE THE COSTS?

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

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or

biospecimens 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, documents, or biospecimens protected by this Certificate 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); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate 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 by the National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality 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.

Audio recordings will be stored on a secure server that is password protected and only accessible to study team members. Audio recordings will also be shared securely with a service provider who will transcribe these recordings. We will retain recordings until all data analysis is complete. At that time any research information will either be destroyed or it will be de-identified and kept for an indeterminate period of time. During study activities, you may request that recordings be stopped at any time.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid up to \$100 at the end of the study if you complete all the scheduled assessments. If you withdraw for any reason from the study before completion you will be paid \$25 for each assessment completed and \$25 if you complete the follow-up interview.

To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the National Institutes of Health. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you] and/or [information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: questionnaire information, text message responses, interview information, and some information from your medical record.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you (“your health information”) may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant’s original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Stephanie Sohl, PhD that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Stephanie Jean Sohl, Ph.D.
Assistant Professor
[REDACTED ADDRESS]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. 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 Web site at any time.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because new information becomes available, you had an unexpected reaction, or because the entire study has been stopped.

Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness

to continue to participate in the study. Clinically relevant research results will not be disclosed to you on an individual basis.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Stephanie Sohl, PhD at [REDACTED].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [REDACTED] or the Research Subject Advocate at [REDACTED].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed): _____

Subject Signature: _____ Date: _____ Time: _____ am pm

Person Obtaining Consent (Printed): _____

Person Obtaining Consent: _____ Date: _____ Time: _____ am pm