Informed Consent

Please complete the survey below.

Thank you!

You may save or print a blank copy of this consent form for your records if you wish. After you submit this form, you will be offered the opportunity to save or print a signed copy of this consent form.

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VUMC Institutional Review Board

Informed Consent Document for Research Study Title: Pilot Testing of the Body Image after Head and Neck Cancer Treatment Program

PI: Bethany Andrews Rhoten, PhD, RN

Version Date: 1/31/22

Date of IRB Approval: XX/XX/XX

Date of IRB Expiration: XX/XX/XX

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1) Name of Participant:

(First Last)

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2) Age:

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information: The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. The purpose of this research study is to determine if a web-based educational program, The Body Image after Head and Neck Cancer Treatment Program, is feasible and acceptable to patients who have been treated for head and neck cancer and have body image concerns.

If you agree to participate, you will be asked to complete web-based questionnaires about how you view your body. This will take approximately 30 minutes. We will collect demographic and cancer treatment history information from your medical record.

After completing the questionnaires, we will give you access to a six-week web-based program designed to address many common body image concerns survivors have after head and neck cancer treatment. You will spend approximately 30 minutes each week completing program activities which are all online and can be completed from anywhere with an internet connected device (smart phone, tablet, computer).

After completing the six-week program, you will again complete web-based questionnaires about how you view your body. You will also complete a survey indicating how much you liked or disliked the program. This will take approximately 30 minutes.

One month after completing the program, we will, again, you to complete web-based questionnaires about how you view your body. This will take approximately 30 minutes.

Possible benefits of this study may include feeling better about your body, but this is not guaranteed. Potential risks include feeling uncomfortable when thinking about your body.

Your participation will not affect your regularly scheduled medical care. We expect to enroll 20 individuals in this study.

Detailed Information:The rest of this document includes detailed information about this study (in addition to the information listed above).

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:

There are no physical risks to you by joining this study. The topics in the program and the questions you will be asked may be sensitive in nature and make you feel uncomfortable. You may be asked personal questions that you find distressing. You will be encouraged to take your time when answering questions and you may refuse to answer any question(s) that you do not wish to answer.

There is a risk of a loss of confidentiality of your personal information as a result of participation in this study. Electronic data will be stored using password-protected files only accessible by the study team through password-protected computers.

There may be risks that are unknown at this time.

Good effects that might result from this study:

You may not benefit from study participation.

The benefits to science and humankind that might result from this study: If feasible, acceptable, and efficacious, this program may provide a low-cost, easily accessible way for head and neck cancer survivors to address and navigate through body image concerns after treatment.

Procedures to be followed:

After providing informed consent, study staff will collect the following information from your medical record: age, sex, gender identity, race, ethnicity, marital status, sexual orientation, living situation, educational attainment, insurance, employment, e-mail address, body mass index, cancer stage and type, cancer treatment details, and reconstructive treatment. Study staff will contact you to find out any information that cannot be found in the medical record.

You will be asked to fill out questionnaires about your body image and coping strategies before receiving The BIHNC Program. This will take approximately 30 minutes.

After completing the questionnaires, you will be emailed a link to complete the BIHNC Program:

• During Week 1, you will view content which covers an introduction of body image and common concerns; this will take approximately 1 hour.
• During Week 2, you will respond to questions about what you learned in Week 1; this will take approximately 1 hour.
• During Week 3, you will view content about coping with appearance changes; this will take approximately 1 hour.
• During Week 4, you will respond to questions about what you learned in Week 3; this will take approximately 1 hour.
• During Week 5, you will view content about coping with changes in your function; this will take approximately 1 hour
• During Week 6, you will respond to questions about what you learned in Week 5; this will take approximately 1 hour.

Directly after completing the BIHNC Program, you will again fill out questionnaires about your body image and coping strategies as well as a program evaluation form. This will take approximately 45 minutes.

One month after completing the BIHNC Program, you will again fill out questionnaires about your body image and coping strategies. This will take approximately 30 minutes.

You may receive $45 for completing all elements of the study ($15 per each set of surveys). Individuals who wish to receive $45 must complete a payment form which includes name, address, phone number, email address, and social security number.

Payments for your time spent taking part in this study or expenses:

In return for your time and effort, you may be paid $45 for participation in this study ($15 for each set of completed surveys).

Costs to you if you take part in this study:

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

Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Bethany Rhoten, PhD, RN at [redacted]

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Nothing will happen if you decide to stop being in this study.

Clinical Trials Registry:

A description of this clinical trial will be available on 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.

Confidentiality:

The PI, Bethany Rhoten, PhD, RN will monitor study progress and is responsible for the safety of participant data collected by Vanderbilt University. All study data will be collected via self-report or medical record extraction and maintained in REDCap, a secure data collection and storage program.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give our your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

Privacy:

Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name.

All study data will be stored in REDCap, a secure, password protected database. PI, Bethany Rhoten, PhD, RN will have access to study data along with trained study personnel. All individuals accessing data will maintain participant privacy and will only access the data for study analysis purposes.

Individually identifying information will not be maintained as part of study data beyond facilitating participant incentives.

Data analysis will occur in aggregate with deidentified data. Participant payment forms will be kept separately from study data.

Study Results:

Study results will not be individually disclosed to research participants.

Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Vanderbilt University Medical Center may share the results of your study and/or non-study linked body image survey data, as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the VUMC Institutional Review Board, Vanderbilt University, the Vanderbilt-Ingram Cancer Center Scientific Review Committee, and the Vanderbilt-Ingram Cancer Center Data and Safety Monitoring committee. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Rhoten in writing and let her know that you withdraw your consent. Her mailing address is [redacted] At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

3) I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

○ Yes ○ No

4) Date:

(Date of Volunteer Signature)

5) Signature of patient/volunteer:

(Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign.)

6) Consent obtained by (please enter full name and title):

7) Date and Time:

(Date and time of staff signature.)