Permission to Take Part in a Human Research Study

Georgetown University

Title: Pilot Randomized Controlled Trial of Use of a Website about Radioactive Iodine Symptom Management in Patients with Thyroid Cancer

Location: MedStar Georgetown University Hospital (MGUH)

Key Information: You have been invited to join a research study. The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you do not understand before deciding whether or not to take part.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you 1) were diagnosed with differentiated thyroid cancer (papillary or follicular carcinoma), 2) received RAI treatment in the past three years, 3) are experiencing symptoms from RAI treatment, 4) are able to read in English, 5) have the ability to understand the consent form, 6) are 18 years of age or older, and 7) have a computer, laptop or smartphone with internet connectivity.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

Patients often do not have enough information and resources for managing RAI symptoms. The purpose of this study is to see if a website for radioactive iodine (RAI) symptom management is feasible and acceptable among adults who have complete RAI treatment. Participants will be randomly assigned (like a flip of a coin) to receive the link for one of two different websites with information about RAI symptom management. We are investigating the helpfulness of two different websites to assist patients like yourself in managing RAI symptoms.

How long will the research last and what will I need to do?

The research study will last for approximately *twelve weeks*. If you join the study, you will be asked to sign this consent form. You will be given a copy to keep. The general procedures include completing three online surveys and looking through a website. A detailed description of study procedures are below.

Regardless of group, you will be asked to complete online questionnaires at three-time points throughout the course of this study, which will ask about RAI symptoms, symptom interference, overall well-being, and emotional well-being.

Initial Survey (Baseline):

If you agree to participate, we will ask for your electronic consent and ask you to complete baseline surveys on a secure website that should take about 20-30 minutes to complete. You will receive a $40 gift card in appreciation for completing the initial survey.

After the initial survey (baseline), you will be "randomized" into one of two study groups described below. Randomization means that you are put into a group by chance, like flipping a coin. Neither you nor the study staff can choose the group you will be in. You have an equal chance of being placed in either group.

RAI Websites:

We ask that participants open the link they receive in their email and look through the website (at their own pace and on their own schedule). Each of the two different websites has information about RAI symptoms but presents the information in different ways. We want to learn which one might work best for patients who are managing symptoms (such as dry mouth, changes in taste, dry eyes, etc.) related to RAI treatment. No identifying or medical information will be requested on either website.

Text Message (SMS) Reminders:

After you are randomly placed into a group, as part of this study, you will receive a brief weekly text message (SMS) reminding you to visit and use the assigned study website. These reminders are intended to support your engagement with the study and are optional. The messages will not contain any personal or sensitive health information. You may choose to stop receiving these messages at any time by letting the study team know.

Follow-up Surveys (4-weeks and 12-weeks after using the website):

After ***4 weeks we will follow up with you to complete another survey.*** These questions will be similar to the first survey you complete. We will send you the follow-up survey through a secure electronic system called REDCap, which will take about 20-30 minutes to complete. You can also complete the survey over the telephone with a member of our team if preferred. You will receive a $40 gift card in appreciation for completing the follow-up survey.

After *12 weeks we will follow up with you to a final survey (T3*). We will send you the follow-up survey through a secure electronic system called REDCap, which will take about 10 minutes to complete. You can also complete the survey over the telephone with a member of our team if preferred. You will receive a $15 gift card in appreciation for completing the T3 survey.

In appreciation of your participation in the study, you will receive gift cards worth $40 (at baseline) $40 (at 4 weeks), and $15 (at 12 weeks) for a possible total of $95 for the 3 total surveys (baseline, 4 weeks, and 12 weeks follow-up survey). This is to thank you for your help with our research.

After completing the follow-up survey, you may be invited to participate in a brief interview to share your experience with the website. This interview will be conducted by phone or online via Zoom and will last approximately 60 minutes. Please note that not all participants will be selected for this *optional* interview. If you are invited and choose to complete the post-study interview, you will receive a $20 gift card in appreciation of your time.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

Participating in this study is voluntary. You can decide not to join or leave the study at any time. If you decide not to join or leave, it won't change the medical care you usually receive, your relationship with your doctors and staff, or your rights to any benefits you're entitled to.

By signing this form, you **do not** lose any of your legal rights.

We do not expect this study to put you at risk or cause increased discomfort. This study is designed to provide information, tools, and resources to manage ***mild to moderate*** symptoms related to RAI treatment. If at any point while responding to the surveys you feel distressed or experience any kind of anxiety, please reach out to us at (202) 687-9319 *or* ***cancercarestudy@georgetown.edu***, and a study staff member will help direct you to the right resources or assistance. Additionally, contact your regular care team. Please feel free to skip any questions that make you feel uncomfortable.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include a website that provides tools and information on how to manage symptoms related to RAI treatment.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate.

Your alternative to participating in this research study is to not participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at cancercarestudy@georgetown.edu or 202-687-9319.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (202) 687-1506 or irboard@georgetown.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

How many people will be studied?

We expect to recruit approximately 88 participants diagnosed with DTC and received RAI treatment within the past 3 years.

What happens if I say yes, I want to be in this research?

- You will sign this consent form.
- Complete an initial survey(baseline) about symptoms related to RAI treatment, mood and confidence in managing symptoms.
- You will be randomized into one of the 2 study groups. Randomization is like flipping a coin in the air. We cannot guarantee which group you will be in.
- After randomization, we will send you instructions for accessing the website to which you have been randomly assigned.
- You will receive a link to respond to a follow-up survey at 4 weeks and 12 weeks.
- You will receive weekly text (SMS) reminders to utilize your assigned website.
- You may be asked to complete a 60-minute interview about your experience using the website.
- You will receive gift cards after each survey worth $40 (at baseline) $40 (at 4 weeks) $15 (at 12 weeks) for a potential total of $95.
- You will receive an additional $20 gift card *only if* you complete the 60-minute interview.

What happens if I say yes, but I change my mind later?

You have the right to withdraw from the research study at any point, and this decision will not be held against you in any way. Your participation is entirely voluntary, and you can choose to leave the study whenever you wish, without facing any consequences.

If you decide to leave the research, contact the study staff at cancercarestudy@georgetown.edu. We will use the responses that you provided up until the time you decided to leave. If you do not want any of your responses used in this study, please let us know directly and we will remove your responses.

Additionally, it's important to know that all of your information collected during the study will be stored securely in an encrypted and secure database called REDCap. Georgetown University manages this database, and strict measures are in place to protect your privacy and confidentiality.

Even if you decide to withdraw from the study, we will still retain and use the data you have already provided for data analysis. However, your personal information will continue to be kept confidential and will not be shared beyond the research team.

Is there any way being in this study could be bad for me? (Detailed Risks)

We do not expect that this study will put you and risk or cause any discomfort. It is possible that some questions may generate worry for some individuals. Members of the research team have been conducting research with human subjects related to cancer over a decade and have experience managing participant discomfort. If the rare circumstance arises Dr. Carr is a licensed clinical psychologist who can make referrals if needed.

For more information about risks and side effects, contact Alaina L. Carr, PhD at 202-687-0958.

Other possible risks include loss of confidentiality. There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it cannot be guaranteed.

To help prevent the loss of confidentiality, no names or medical record numbers will be used on the surveys. Study staff will assign a research identification number to each participant that will be used on the surveys. Only Dr. Carr and the study staff will have access to the key linking research identification numbers to participants' names. This key will be kept in a secure electronic file that is password protected.

Policy/Procedures or Research Related Injuries

The Policy and Procedure for the Georgetown University Medical Center and MedStar Health Research institute are as follows:

The survey links and website link will be sent to your email. This study involves reading information on a website and answering questions; thus, we do not anticipate any injuries. We will make every effort to prevent study-related injuries and illnesses. If you are injured or become ill while you are in the study and the illness or injury is due to your participation in this study, you will receive necessary medical care. The costs of this care will be charged to you or your third-party payor (e.g., Sponsor, or your Health Insurer) in the usual manner and consistent with applicable laws. No funds have been set aside by Georgetown University, Georgetown University Hospital, MedStar Health Research Institute, or their affiliates, to repay you or compensate you for a study related injury or illness.

What happens to the information collected for the research?

Efforts will be made to protect your medical records and other personal information to the extent allowed by law. However, we cannot guarantee absolute confidentiality. The surveys will be sent

through REDCap, an encrypted platform used by Georgetown University, ensuring secure transmission and storage of your responses. You will not be identified in any reports or publications resulting from this study. All information collected in this study is protected by a Certificate of Confidentiality from the National Institutes of Health. We will not release any of your information without your permission.

You will not be identified in any reports or publications resulting from this study. In addition to the researchers and research institution(s) conducting this study, organizations that may request to inspect and/or copy your research and medical records for quality assurance data analysis and other research related and operational or administrative purposes, include groups such as:

The National Cancer Institute, MedStar Health Research Institute, Georgetown University, MedStar Health Research Institute-Georgetown University Institutional Review Board (IRB), federal research oversight agencies.

Please note that administrative personnel involved in processing your payment for participation will be aware of your identity.

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies if you indicate that you would like to be contacted about future research study opportunities.

We will submit data from this study to an open-access repository. All private information that could identify you will be removed or changed before data are put in an open-access repository. Anyone can use information from an open-access repository for any purpose.

Federal law provides additional protections of your medical records and related health information. These are described in an attached document.

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 website at any time.

HIPAA Authorization

We are committed to respecting your privacy and to keeping your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information including the health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. The health information we may collect from you and use for this research includes:

- All information in a medical record
- Your name
- Your telephone number and email address
- The date you were diagnosed with thyroid cancer
- The date of your thyroid cancer surgery

- Details about the "pathology" from your thyroid cancer
- The date of your radioactive iodine therapy
- The dose of your radioactive iodine therapy
- Medical history

The following entities may receive your health information:

- Administrative staff members from the MedStar Health Research Institute-Georgetown University Institutional Review Board (IRB) Office and its agents, and members of the Institutional Review Board.

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Georgetown University, MedStar Health, etc. and its clinical partners (or affiliates): the Georgetown University Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or Georgetown University policy.

The following entities may receive your health information:

- Authorized members of the Georgetown University and MedStar Health workforce who may need to see your information, such as administrative staff members from the Georgetown University Institutional Review Board (IRB) Office and its agents and members of the Institutional Review Board.
- Other Georgetown University and MedStar Health research centers and Georgetown University contractors and MedStar Health contractors who are also working on the study
- Study monitors and auditors who make sure that the study is being done properly.

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those people may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire in 7 years (March 2032)

After the expiration date, Georgetown University and MedStar Health may not gather new information about you, or use or disclose your personal health information collected in this study for any purpose other than the research study described in this consent unless Georgetown University and MedStar Health obtains permission to do so from you.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Alaina L. Carr, PhD
Institution: Georgetown University Medical Center
Department: Department of Oncology
Address: 2115 Wisconsin Ave., NW, Suite 300
Washington, DC 2007

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study if you do not allow this. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include any medical condition, event, or situation that occurs such that continued participation in the study would not be in the best interest of the subject or a participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation.

New Findings

Once the data from the study has been thoroughly analyzed and published, we are committed to sharing the results with you. We will send you a summary of the results at the conclusion of the study.

What else do I need to know?

If you agree to take part in this research study, we will pay you up to $115 in the form of a gift card for your time and effort.

Signature Block for Capable Adult
Your signature documents your permission to take part in this research.

Signature of subject	Date

Printed name of subject

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