What can I expect if I join the STRONG study?

Our purpose: To evaluate the best method of teaching self-advocacy skills to women in the hopes of improving their quality of life.

TODAY: Complete and return baseline questionnaires

$30

~45min

Randomly assigned group

What is self advocacy?

Self-advocacy is the ability to stand up for your needs, values, and priorities when it comes to your healthcare.

Tablet Program Intervention

Complete 3 month surveys

$20

~30min

Optional phone interview

$15

Complete 6 month surveys

$20

~30min

Optional phone interview

$15

Self-Advocacy Paper Guide

Complete 3 month surveys

$20

~30min

Surveys can be done on paper, online, or even over the phone!

Complete 6 month surveys

$20

~30min

Option to receive tablet intervention

The tablet is yours to keep! Congratulations on completing the study!

University of Pittsburgh

UPMC | HILLMAN CANCER CENTER

Contact info:
selfadvocacy@pitt.edu
412-624-0279

University of Pittsburgh

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: Efficacy of a self-advocacy serious game intervention for women with advanced cancer

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SOURCE OF SUPPORT: National Cancer Institute

Key Information

- **This is a research study**: You are being asked to participate in a research study. Research studies only include people who want to be a part of the study. The study team will review the study with you so that you can choose

whether to take part in the study or not. You can ask questions and take your time in deciding if you want to participate.

- **Study purpose**: The purpose of this study is to evaluate a program to teach self-advocacy skills to women with advanced cancer. Self-Advocacy skills help you stand up for your needs, values, and priorities during cancer. The study lasts six months. There are three times in which we would contact you. You only need to meet us in-person once (the day you join the study).

- **Study risks**: There are risks associated with this study. The first risk is that your personal information would not be private. The second risk is that you would become distressed because of the study. The two risks are unlikely to occur.

  Study benefits: Participants may potentially gain knowledge on self-advocacy.

- **Alternatives**. A paper guide to self-advocacy.

Why is this research being done?

We are evaluating a program to help patients with cancer stand up for their needs, values, and priorities during their cancer journey. We call this "self-advocacy." Self-advocacy aims to improve your health and relationship with loved ones and your healthcare team.

You will be randomly assigned to one of two study groups. Either you will receive the self-advocacy program on a computer tablet, or you will receive a paper self-advocacy guide. We will ask you to complete surveys and

interviews. Your participation will determine if the self-advocacy program helps patients' health and quality of life.

Who is being asked to take part in this research study?

You are being invited to take part in this research study because you are an adult female recently diagnosed with advanced cancer. We will include about 336 women with cancer in this study.

What procedures will be performed for research purposes?

This is a randomized clinical trial. If you agree to participate, you will be randomly selected to one of two groups. The first group will receive a self-advocacy program on a tablet. The second group will receive a paper self-advocacy guide. Randomization is like flipping a coin. You will have the same chance of being in either group.

Self-Advocacy Program Group: If you are selected for the intervention group, we will give you a computer tablet with the self-advocacy program loaded onto it. This program teaches self-advocacy skills by showing you women diagnosed with cancer and having you make decisions for them to keep them healthy and strong.

Paper Self-Advocacy Group: If you are selected for the paper self-advocacy group, we will give you a paper guide to self-advocacy published by the National Coalition for Cancer Survivorship. This guide reviews a variety of ways in which individuals with cancer can speak up for their needs and priorities. If you would like, at the end of the study you can receive the self-advocacy program on a tablet.

For both groups, you can use the program or paper guide at your leisure, especially during the next three months. We will send you reminders every other week for the first three months to review the self-advocacy program or paper guide. We recommend reviewing the program or paper guide for 15 minutes once a week.

Data Collection: Our study team will review your medical record to collect information about your health and cancer diagnosis, cancer treatment, and use of healthcare services.

You will be in this study for **6 months** and asked to complete questionnaires and interviews.

- All participants will complete questionnaires described above at baseline and at two follow-up times (in 3 months and 6 months). The total time for questionnaires will be between 1.5 hours to 2 hours.
    - Baseline questionnaires will take about 45 to 60 minutes.
    - Follow-up questionnaires will take about 20 to 30 minutes.
    - Questionnaires ask about your physical and emotional health, your quality of life, how you advocate for yourself, and different healthcare services you've used.
    - Questionnaires can be completed on paper, online, or by phone. If you need assistance with completing online questionnaires, we are available to help.
- Participants in the intervention group may be asked to complete phone interviews at 3 months and 6 months. Each interview will take about 30 minutes (total of 30 minutes or 60 minutes). These interviews will be recorded.

What are the possible risks, side effects, and discomforts of this research study?

This is a very low risk study, but you should be aware of the risks.

1. The major potential risk is a breach of confidentiality, but we will do everything possible to protect your privacy. All researchers involved in this study have been thoroughly trained to maintain your privacy. Online questionnaires use a secure, encrypted website. Audio-recordings will be encrypted and stored on a password-protected, encrypted computer. All information will be identified only by a case number. The information linking these case numbers with your identity will be kept separate from the research records. All paper questionnaires and information you provide will be kept by the Principal Investigator in a locked file cabinet within a locked office at the University of Pittsburgh School of Nursing. Your identity will not be revealed in any description or publications of this research.

We will protect your privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside

UPMC or the University. Confidentiality during Internet communication activities cannot be guaranteed, and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study. Text messages are not encrypted or secure during their transmission. Text messages could be intercepted and used by others not associated with this study.

2. Another possible risk of this research study may include stress related to the intervention, questionnaires, and interviews. In case any questions cause you stress or discomfort, you can take a break from completing the intervention, questionnaires, and interviews or decide not to answer questions. If you begin to feel distressed during the study, your nurse can refer you to the licensed clinical social worker at the Hillman Cancer Center who is trained in supporting patients. If we identify any concerns about your health, especially your mental health, during the study we will reach out to you with resources and support and reach out to your oncologist. You will be promptly notified if any new information we learn during this research study may cause you to change your mind about continuing to participate in the study.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. The researchers also cannot provide your information as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The Certificate does not stop reporting that federal, state or local laws require including threats to harm yourself or others.

What are possible benefits from taking part in this study?

Participants may potentially gain knowledge on self-advocacy. The creation and use of this self-advocacy program may benefit female cancer survivors in the future.

What are alternatives to taking part in this study?

You can receive a paper guide to self-advocacy published by the National Coalition for Cancer Survivorship.

Will I be paid if I take part in this research study?

Participants will be paid for each completed questionnaire: $30 at baseline and $20 for each follow-up questionnaire. Participants will be paid $15 for each completed interview.

Who will know about my participation in this research study?

Any information about you obtained from this research will be kept strictly confidential. All records related to your involvement in this research study will be stored in a locked file cabinet and an encrypted password protected file in a locked room at the University of Pittsburgh School of Nursing. Your identity on these records will be indicated by a case number rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research records. You will not be identified by name in any publication of the research. All records will be retained by us for a minimum of seven years.

It is possible that we may use the information obtained from this study in other research studies examining self-advocacy among patients with cancer. This information may also be shared with other researchers here, and at other research centers, but those researchers will never be provided with any personal identifiers that would allow them to learn who you are.

Will this research study involve the use or disclosure of my identifiable medical information?

Yes. As part of this study, we are also requesting your authorization or permission to review your medical records to obtain past and medical information from hospital and other medical facilities. We will obtain information concerning cancer history; general health; past cancer treatments; any hospital admissions; and visits to the Emergency Department, visits to the cancer clinic, visits to supportive care providers, and communication with your cancer care team. We will collect this information to describe your cancer experience and the type and amount of healthcare services you use. We will use this information with the questionnaires you will complete to describe all participants' experiences

(and not individual participants) and look for commonalities and differences among participants. If any protected health information is discussed while you are being audio-recorded, this information will be deleted from the audio tape and not transcribed. This authorization is valid for an indefinite period of time, or until you formally withdraw your authorization.

This identifiable information will be made available to members of the research team for an indefinite period of time. That medical information, as well as information obtained during this research study, may be shared with other groups, possibly including authorized individuals the University of Pittsburgh Research Conduct and Compliance Office, for the purpose of monitoring the study.

Where can I find information about this research study?

A description of this clinical trial will be available on https://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.

Is my participation in this research study voluntary?

Your participation in this research study is completely voluntary. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

Will I be billed for participation in this research study?

Neither you, nor your insurance provider will be charged for the cost of the procedures performed only for the purposes of this research study. You and/or your insurer will be billed in the usual manner for your standard medical care (care you would receive even if you were not participating in this research study).

May I withdraw, at a future date, my consent for participation in this research study?

You may withdraw, at any time, your consent for participation in this

research study and your authorization to allow the research team to review your medical records by making the request in writing. However, if you do so, you will no longer be permitted to participate in this study. Any information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above unless you request elimination of your data.

If you decide you no longer wish to participate after you have signed the consent form, you should contact Dr. Thomas (412-624-3799). Your decision to withdraw from this study will have no effect on your current or future relationship with the University of Pittsburgh. If you would like additional information, you may contact the Research Office at 412-692-5551*. If you have any questions about your rights as a research subject or wish to talk to someone other than the research team, please call the University of Pittsburgh Human Subjects Protection Advocate toll-free at 1-866-212-2668.*

If I agree to take part in this research study, can I be removed from the study without my consent?

If you are ineligible to participate, you will be removed from the study. If you are eligible to participate, you will not be removed from this study without your consent.

Voluntary Consent

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any part of this research study during this study. Any future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the Human Research Protection office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation. By signing this form, I consent to participate in this research study. A copy of this consent form will be given to me.

_____ _____ _____

Participant's Signature Printed Name of Participant Date

Investigator Certification

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date