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Fred Hutchinson Cancer Center
University of Washington

Consent to take part in a research study:

Escape Room: A gamified approach to learning about cancer nutrition information

Principal Investigator: Megan J. Shen, PhD, Fred Hutchinson Cancer Center
Telephone: 206-667-4172

Important things to know about this study.

You are invited to participate in a research study. The purpose of this research is to develop and improve an escape room intervention about cancer nutrition information.

People who agree to join the study will be asked to participate in 2 study visits over 4 weeks. The study involves completing surveys and participating in a brief interview to get your feedback on the escape room intervention. All study steps can be completed remotely.

You do not have to join this study. Although the study will not benefit participants directly, we hope the information we learn will help breast cancer patients learn about accurate cancer information in the future. The study procedures could cause some emotional discomfort, as described below in this form.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

We would like you to join this research study.

We are doing a research study to develop and improve an escape room intervention about cancer nutrition information. We want to know if the escape room intervention can help improve breast cancer patients' ability to navigate online access to nutrition information.

Since you are a breast cancer patient, we would like to ask you to join this study. We will enroll up to 40 breast cancer patients. Although the study will not benefit participants directly, we hope the information we learn will help people with breast cancer in the future.

If you agree to be in this study we will do the following:

- **Medical records review:** Review your medical records for information about your health and cancer.
- **Surveys:** You will be asked to complete surveys. The surveys will ask about your demographics, cancer history, and nutrition information source preferences. You will complete a baseline and a post-game survey remotely. We will provide you with a link to the surveys via your preferred method of communication, whether that be email or text message. The surveys take about 15 to 30 minutes each to complete.
- **Escape room intervention session via a video-calling platform:** This is the experimental portion of the study**.** You will be asked to participate in an escape room game session. After completion of the baseline, you will be sent a link via your preferred method of communication, whether that be email or text message, to sign up for an escape room game session. The game follows a fictional company that is trying to sell their nutritional product to cancer patients. You will be asked to solve puzzles to investigate the potential impacts of the company's product.

  The escape room is a collaborative game. You will play the game with other players (3-5 players in total per group). The length of the game is approximately 30-45 minutes depending on how quickly participants solve the puzzles. The game will be played online via a video-calling platform (i.e. Zoom). Following the game, your group will participate in a 15-20 minute debrief session with the game host. You will receive a reminder a couple of days ahead of the game session via your preferred method of communication.
- **Group debrief for about 15-20 minutes by video-calling platform:** Immediately after the escape room session, we will ask you to take part in a 15-20 minute debrief session to give your feedback on the escape room game. The goal of the debrief is to understand how participants' attitudes and feelings about cancer nutrition information may have been impacted by the escape room experience. The debrief will also explore how participants feel about health information and their comfort level with questioning the source and nature of the information. Your answers will be kept strictly confidential. This debrief will be followed by the post-game survey.
- **Permission to audio record:** If you agree to participate in this study, your visit with our study team member during which you complete the escape room session and debrief will be audio recorded. All recordings will be confidential, saved in the study team's password-protected computer, and will be destroyed after the study is completed. If you do not give us permission to audio record our interview with you, you are not eligible to participate in the study. Please note that Zoom captures audio and video during recordings. For the purposes of this study, we will only save the audio recording of the session.
  - Do you give us permission to audio record our debrief interview with you? (record patient response):

    Yes ___ No ___

You do not have to be in this study. You are free to say yes or no, or to drop out after joining. There is no penalty or loss of benefits for saying no or dropping out. Whatever you decide, your regular medical care will not change.

If you leave the study, your information cannot be removed from the study records.

How did you get my name?

We are screening patients from Fred Hutchinson Cancer Center. The doctor treating you thinks you may be eligible for this study.

Do I have to participate in the whole study?

Each part of the study is completely voluntary. You may choose to join all, some, or none of the study activities. You may stop the telephone or video-calling interview at any time, or choose not to answer some questions.

Will you pay me to be in this study?

We will pay you $25 for the first study visit and $50 for the second study visit (for a total of $75).

Study visit 1: Baseline - $25

Study visit 2: Escape room session + debrief and post-game survey - $50

How much will this study cost me?

There are no costs for being in this study.

Protecting your Privacy as an Individual and the Confidentiality of Your Personal Information

Some organizations may need to look at your research records for quality assurance or data analysis. These include:

- Researchers involved with this study.
- Fred Hutchinson Cancer Center and University of Washington.
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Center IRB. An IRB is a group that reviews the study to protect your rights as a research participant.
- US National Institutes of Health, National Cancer Institute, Office for Human Research Protections, and other agencies as required.

We will assign a study identification number to your research record. The researchers doing research on data collected from you will not have access to your name or other personal information. They will know the study identification number only. Thus the risk of someone connecting any study information with you as an individual is unlikely. However, your personal information may be released by accident.

We will keep your personal information confidential. But we cannot guarantee total confidentiality. Your personal information may be disclosed if required by law. For example, we are required to report certain diseases and infections to public health authorities. We are also required to report suspected abuse or neglect of children and vulnerable adults. Workplace safety rules may require health workers to contact you about lab tests. Or a court may order that study information be disclosed. Such cases are rare.

We will not use your personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

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.

At the start of the study, this research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate generally we would not have to give out identifying information about you even if we were asked to by a court of law. We would use the Certificate to resist any demands for identifying information. The Certificate may not last the duration of the research. Talk to the study researcher if you have questions about this.

We could not use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person.

This protection has some limits. We would voluntarily provide the information:

- To a member of the federal government who needs it in order to audit or evaluate the research.
- To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly.
- To someone who is accused of a crime, if they believe that our research records could be used for defense.
- To authorities, if we learn of child abuse, elder abuse, or if participants might harm themselves or others.

What will my information be used for?

Your information will be used for the purposes of this study. We will use the data collected from surveys and your feedback given to us during the debriefing interview to improve the escape room intervention for use with future cancer patients.

During this study, we do not expect any test results that would affect your care, so we do not plan to return results to you.

Will my information be used for future research?

Your information will not be used for any research other than this study.

HIPAA Authorization for the Use of Patient Information for Research

By signing this consent form, you permit your patient information to be shared with Fred Hutchinson Cancer Center, its staff, and others who work with them. In this section of the consent form, the term for all these people is "Researchers." Their individual names appear in this consent form.

Federal and state laws require that you give your permission for the Researchers to see and use patient information. A federal law known as the Health Insurance Portability and Accountability Act (also called "HIPAA") protects the confidentiality of patient information created and used by your health care providers. Once patient information is disclosed to the Researchers, it will no longer be protected by HIPAA and could be re-disclosed. However, other laws do apply to the Researchers that require them to protect the confidentiality of your information.

The Researchers will use the patient information only for the purposes named in this form.

1. The patient information to be obtained and used includes:

- All patient information in your medical records needed by the Researchers for the Study. It also includes information in your records that can identify you. For example, it can include your name, address, phone number, birth date, and medical record number.

- The specific patient information that will be obtained and used for the Research is described below:
    - Hospital discharge summary
    - Radiology records
    - Medical history/treatment
    - Consultation
    - Radiology films (like X-rays or CT scans)
    - Laboratory/diagnostic test
    - EKG report
    - EEG report
    - Psychological testing
    - Pathology reports
    - Operative report (about an operation)
    - Pathology specimen(s) and/or slide(s)
    - Diagnostic imaging report
    - Dental records

- Cancer diagnosis

2. What the Researchers may do with patient information.

The Researchers will use your patient information only in the ways described in this consent form. They may also share your patient information with certain people and groups. These may include:

- The sponsor of the study. A sponsor provides support for research studies. The sponsor reviews the study. By law, Researchers share some information with the sponsor.
- Government agencies, review boards, and others who watch over the safety, effectiveness and conduct of the research
- Others, if the law requires.

This consent form describes who will have access to your patient information. It also describes how your information will be protected. By law, the Researchers are required to protect the confidentiality of your information. You may ask questions about what the Researchers will do with your information and how they will protect it.

3. How long the permission will last?

The permission for the Researchers to obtain and use your patient information will end when the Researchers complete the research study AND any review of the research study is completed.

4. Canceling your permission.

You may change your mind and take back your permission anytime. To take back your permission, write to: Dr. Megan Shen at mshen2@fredhutch.org. If you do this, you may no longer be allowed to be in the study. The Researchers may still keep and use any patient information they already have. But they can't obtain more patient information about you for the study unless it is required by a federal agency that reviews the study.

5. Giving permission

You give your permission for the use of your patient information by signing this consent form.

In addition to signining this consent form, federal and state laws require that you provide specific permission for certain types of information to be shared with the Researchers. These types of information include any diagnosis or treatment of HIV/AIDS, sexually transmitted diseases, drug and alcohol abuse, mental illness or psychiatric conditions. Please note that federal law prevents the use of this type of information to criminally investigate or prosecute alcohol or drug abuse patients.

I give my specific authorization for this information to be released:Yes ___ No ___

Other information.

If you have questions or complaints about this study, please call Dr. Megan Shen at 206-667-4172 or email Dr. Shen at mshen2@fredhutch.org. You can also contact Co-Investigator Chris Coward at 206-437-4592 or email him at ccoward@uw.edu. If you have questions about your rights as a research participant, call the Director of the Fred Hutch Institutional Review Office at 206-667-5900 or email irodirector@fredhutch.org. You can also call the University of Washington Human Subjects Division at 206-543-0098.

There are no physical risks associated with this study. However, there may be some emotional discomfort in discussing your health and cancer. If you experience extreme distress due to study procedures, please contact the researcher on this project, Dr. Megan Shen. She can connect you with a licensed social work clinician on this study.

Will you contact me in the future?

We may contact you about future research opportunities or to update you about the study via a newsletter.

Your rights

- You do not have to join this study. You are free to say "yes" or "no".
- If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.
- During the study, we might learn new information that you need to know. Other information might make you change your mind about being in this study. If we learn these kinds of information, we would tell you.
- If you join this study, you would not have to stay in it. You could stop at any time (even before you start). Your regular medical care would not change. You would have no penalty for stopping, but it would be better not to join the study if you think that you would change your mind later.

Signature

Please sign below if you:

- have read this form;
- had the opportunity to ask any questions you have;
- had the opportunity to discuss the research with the person obtaining consent; and
- agree to participate in this study and authorize your doctors and other health care providers to disclose patient information that identifies you with the researchers.

Participant:

Printed Name	Signature	Date

Protocol: RG1123830
Current consent version date: 02/26/2024
Previous consent version date: 01/31/2024
Copies to: