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

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SPONSOR: Fred Hutchinson Cancer Center

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PROTOCOL SYNOPSIS

Protocol Title	Escape Room: A gamified approach to learning about cancer nutrition information
Protocol Number	
Protocol Sponsor	Fred Hutchinson Cancer Center
Trial Phase	Early Phase/Phase 1
Trial Type	Single arm, open trial
Study Objectives	**Aim 1** To evaluate the feasibility, acceptability, and usability of the escape room game intervention among breast cancer patients in active treatment. **Exploratory Aim 2** To test preliminary efficacy of the escape room game intervention for increasing awareness about types of online misinformation, concern about misinformation, and confidence in the ability to identify misinformation as well as decreasing cancer nutrition misinformation beliefs.
Study Design	Feasibility study (Aims 1 and 2)
Population	Patients with a current diagnosis of breast cancer (Stages I-III) and in active treatment for breast cancer.
Primary Endpoints	Study design and intervention feasibility, acceptability, usability, and potential efficacy of an escape room game will be measured by assessing accrual rate, satisfaction, and usability of the escape room game.
Secondary Endpoints	Awareness and concern about cancer nutrition misinformation and beliefs about cancer nutrition.
Type of Control	N/A (single arm, open trial)
Treatment Group	Escape room game
Treatment Schedule	Intervention (Escape Room Game): - Pre-game baseline survey - Play the misinformation escape room game intervention in groups of approximately 5 and completed debrief exit interview - Post-game survey
Number of participants	N=40 (n=5 breast cancer patients per group)
Estimated duration of study (per participant)	4 weeks
Duration of participation (per participant)	90 minutes

ABBREVIATIONS

Include a table of abbreviations as needed.

EHR	Electronic health record
Fred Hutch	Fred Hutchinson Cancer Center
UW	University of Washington

Table of Contents

1.0 GENERAL INFORMATION

1.1 Protocol Title

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

1.2 Sponsor Information

Fred Hutchinson Cancer Center

1.3 Investigator Information

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1.4 Participating Sites

Fred Hutchinson Cancer Center
University of Washington

2.0 INTRODUCTION TO THE PROTOCOL

2.1 Introduction

The described study will be conducted in compliance with all applicable IRB requirements and associated Federal regulations.

The overarching goal of this research study is to pilot test an escape room intervention for cancer nutrition misinformation designed to reduce vulnerability to believing cancer nutrition misinformation among breast cancer patients. The results of this pilot study will provide necessary preliminary data to apply for an NIH R01 level application to conduct a full randomized controlled trial (RCT) of the escape room game as a potential intervention to increase resistance to cancer nutrition misinformation.

Chris Coward (Co-I) and Jin Ha Lee (Co-I) at the University of Washington (UW), along with collaborator Lindsay Morse (Puzzle Break), previously developed an online misinformation escape room as an interactive learning experience designed to focus on the psychological dimensions of misinformation. Escape rooms are live action-adventure games where teams work cooperatively to solve a series of puzzles. Initial results were encouraging,[1] indicating the game successfully increased awareness of misinformation and confidence in identifying it. Based on this experience, the UW research team and Megan Shen (PI) at Fred Hutch partnered to develop an escape room for cancer nutrition misinformation. This project builds off Dr. Shen's key strengths as a cancer communication researcher and builds on a novel and relevant area of public health – combating cancer misinformation. Expertise from oncologists and cancer nutrition experts about the types of misinformation they encounter in their work with patients was also incorporated into developing the escape room content.

2.2 Background

The COVID-19 pandemic has brought to the forefront both the prevalence and dangers of health misinformation among the U.S. population. Misinformation, or communication about health information that is inaccurate or false, has serious health consequences for those that believe it.[2] The rise of the access to and use of the various sources of information on the internet such as websites and social media has caused the spread of misinformation and disinformation to grow rapidly,[3] creating far-reaching negative consequences on health outcomes. Cancer misinformation, in particular, has become an increasingly prevalent issue that poses a real public health threat to the many cancer patients in the U.S.[4] One area of this landscape is cancer nutrition misinformation, which can propel patients into engaging in health behaviors that may negatively affect their treatment and survival outcomes or avoiding positive health behaviors that may benefit them.

Misinformation around nutrition is prevalent. One study found that health claims such as prevent (41.8%), treat (27.2%), and cure (10.7%) cancer and phrases such as "anti-cancer" or "cancer-fighting" were common among recipes posted to the website Pinterest.[5] Prior research indicates that core components of information seeking such as trustworthiness are critical to determining peoples' likelihood of believing and acting upon misinformation.[2] However, in the context of online information where misinformation thrives, it can be very difficult to determine whether a source is truly trustworthy or accurate. Thus, in turn, makes patients highly vulnerable to cancer nutrition misinformation through online routes of obtaining information. Because proper nutrition is critical to patients being able to receive proper cancer treatment and manage symptoms associated with treatment, it is critical that patients receive access to accurate cancer nutrition information.

Unfortunately, education alone is rarely an effective form of intervention for combating misinformation. This project will build on prior stages of research aiming to develop a gamified approach to building resilience to public health misinformation, with a specific focus on cancer nutrition misinformation. *Gamification* is a promising new target for combating misinformation, as it provides a way to help users learn new skills (such as developing awareness of and resistance to misinformation) through the psychologically non-threatening form of play.[6] This approach involves the creation of an escape room game that will help people detect and resist misinformation through an immersive learning experience which focuses on cognitive biases, emotional triggers, and other affective attributes of misinformation.

2.3 Risks/Benefits

Risks

- Discomfort. There may be some emotional discomfort in discussing misinformation and disinformation rhetoric in relation to health and nutrition related topics. We do not anticipate that this discomfort will be exacerbated by a group setting. Indeed, misinformation researchers use group reflection meetings to mitigate the emotional impact of being exposed to misleading and problematic information. The UW's Center for an Informed Public builds group reflection meetings into research timelines for their student researchers as group reflection on misleading information has allowed researchers to maintain clarity in confusing information environments and provided them with a supportive space to share any concerns around the information they encounter. We anticipate that this same framework will apply to the cancer patient population. Further, the Misinformation Escape Room has been designed using expert insight from in-depth interviews with oncologists and cancer nutrition experts and will be, prior to player testing, evaluated by the same experts to ensure it is appropriate for this specific patient population. Finally, we have proper oversight and monitoring of any adverse events created by participating in group settings in order to ensure an accurate oversight of and response to any potential distress is part of the research plan. Participants can decline to complete the intervention, survey or interview or skip questions at their own discretion.
- Loss of privacy. A risk of taking part in this study is the possibility of a loss of confidentiality. Loss of confidentiality includes having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. We will try to protect your information, but we cannot guarantee privacy. The plans for keeping your information private are described in the 'confidentiality' section of this consent form.

Benefits

- Knowledge gained. Although the study may not benefit participants directly, this study could provide important information on how to address issues of cancer misinformation. Because risks to participants in this study are minor, the risks are reasonable in relation to the expected benefits.
- Financial compensation. Participants will receive $75 for playing the game, participating in a post-game brief interview, and completing baseline and post-intervention surveys.

3.0 OVERVIEW OF STUDY

3.1 Study Objectives

The overarching goal of this research study is to pilot test an escape room intervention for cancer nutrition misinformation designed to reduce vulnerability to believing cancer nutrition misinformation among breast cancer patients. The main aim (Aim 1) is to determine the potential feasibility, acceptability, and usability of the intervention. The secondary aim (Aim 2) is exploratory in nature and designed to determine if there are potential changes in pre/post outcome measures (increasing awareness about types of online misinformation, concern about misinformation, and confidence in the ability to identify misinformation). The results of this pilot study will provide necessary preliminary data to apply for an NIH R01 level application to conduct a full randomized controlled trial (RCT) of the escape room game as a potential intervention to increase resistance to cancer nutrition misinformation.

3.2 Specific Aims

Aim 1

To evaluate the feasibility (1a), acceptability (1b), and usability (1c) of the escape room game intervention among breast cancer patients in active treatment.

Hypothesis 1a: For feasibility, ≥50% of screened eligible patients[7] will enroll in the study.

Hypothesis 1b: For acceptability, ≥70% of patients will rate the intervention as satisfactory (e.g., a "7" or higher on a 10-point Likert scale) on a 10-point Likert-scale item assessing how satisfied they are with the intervention and will recommend this game to others.

Hypothesis 1c: For usability, ≥70% of patients will have a System Usability Score (SUS) of ≥68.

Exploratory Aim 2

To test preliminary efficacy of the escape room game intervention for increasing awareness about types of online misinformation, concern about misinformation, and confidence in the ability to identify misinformation as well as decreasing cancer nutrition misinformation beliefs.

Hypothesis 2: Cancer patients will report increases in awareness about types of online misinformation, concern about misinformation, and confidence in the ability to identify misinformation and reductions in believing cancer nutrition misinformation from pre- to post-intervention.

3.3 Study Population

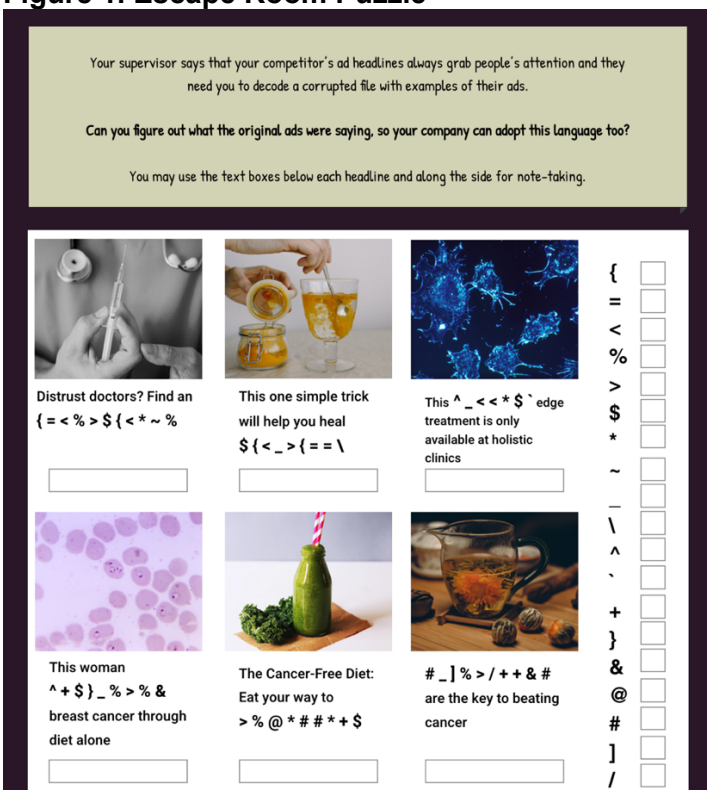
The study includes patients with a current diagnosis of breast cancer and/or are receiving treatment for breast cancer.

3.4 Study Design

Intervention Description

The intervention is an escape room game designed to teach participants how to discern whether cancer nutrition information is accurate or may potentially be misinformation. The content of the game focuses on common tactics used to spread misinformation such as cherry-picking study data, using questionable “expert” influencers, overgeneralization, and misleading headlines. The game is designed to be played in groups of approximately 5, in which players work together to solve a series of puzzles that teaches them about the potential risks of misinformation online. In the present study, the intervention will follow a fictional company (“ZenFusion Wellness") that is trying to sell its nutritional product (The “Evergreen Diet”) in order to make profits. Throughout the game, players are immersed in the narrative while solving puzzles to learn key themes such as the need to talk to their doctors and look for scientific studies and FDA approvals as well as avoid fads and trends, miracle cures, anecdotal evidence, and targeted and clickbait ads. For example, in one puzzle, participants are asked to “decode” the sensationalist ad headlines and use the codebook to find a password. The headlines are designed to mimic programmatic ads often seen at the bottom of websites with text such as “This one simple trick will help you heal naturally” and “This woman conquered breast cancer through diet alone.” **Figure 1** provides a screenshot of the puzzle. Below, we also outline all five puzzles included in the game.

Figure 1. Escape Room Puzzle



- **Puzzle 1:** This puzzle is a visual representation of the spread of strong emotions via social media. Players are shown an unfinished grid puzzle with smiley face emojis depicting different emotions. Players are asked to rearrange pieces of the puzzle, and after doing so, an image will be revealed that gives a clue to the secret password. When the secret password is entered correctly, the game continues.
- **Puzzle 2:** This puzzle is primarily text-based and reflects tactics of misleading advertising. It provides several partially finished headlines related to nutrition. Players are asked to work together to decode the letters / words (e.g., "The Cancer-Free Diet: Eat your way to **>%!*##*+$**" when solved becomes "The Cancer-Free Diet: Eat your way to **remission**"). When solved correctly, players will be able to decode the secret password.
- **Puzzle 3:** This puzzle is in two parts and reflects tactics used to cherry pick data and only present successful outcomes. Part One is a matching game, where players flip over cards and make pairs (each image has a food and a person). Once matched successfully, players begin Part Two, where they match the foods with people that were linked in Part One. This reveals a secret password.
- **Puzzle 4:** This is a Hashi bridge puzzle that requires players to connect nodes in a network. Each player works on their own individual puzzle, connecting dots with one or two lines. Correctly solved puzzles will visually form a letter—all four letters revealed spell out the secret password.
- **Puzzle 5:** This puzzle is a maze and represents individual patient health journeys and how to navigate through uncertainty. Each player solves their own maze by clicking on tiles that will form the correct path associated with images that correspond to parts of the care journey that should be adopted (e.g., scientific studies, consultations with medical professionals) rather than those that should be avoided (e.g., fads and trends, miracle cures). Once all players solve their maze, the secret password is revealed.
- **Final Task:** Before the game ends, players are asked to select an option to finish the story. All options are acceptable and lead to winning the game. Players' discussion of options will preface the next stage of the intervention, which is the hosted debrief.

The game is designed to be played only once by players. It is a collaborative group appropriate for 3-5 players to play together. 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).

At the end of the game, players are expected to be more aware of possible nutrition misinformation that may be online and to be wiser consumers of online information.

Eight groups of approximately 5 participants (n=40 total) will be recruited and grouped together. Participants will be provided a baseline survey prior to their attendance at the session. Participants will play the misinformation escape room game together with the group and take part in a debrief with a member of the research team immediately after completing the game. Finally, participants will be provided with a post-game survey to complete after the game and debrief session.

3.5 Name of Sponsor/Funding Source

Fred Hutchinson Cancer Center, Cancer Consortium Grant (NIH/NCI)

4.0 PARTICIPANT ELIGIBILITY

4.1 Inclusion Criteria (Patients)

Inclusion Criteria:

1) Age 18 years of age or older.
2) English speaking.
3) Able to provide informed consent.
4) Have access to a computer (desktop or laptop).
5) Have been previously diagnosed with breast cancer (Stages I-III) and currently in active treatment for breast cancer.

Exclusion Criteria:

1) No other exclusion criteria.

5.0 PARTICIPANT REGISTRATION

When potential study participants are identified, Fred Hutch research staff will enter their information into the secure REDCap database, as well as into OnCore CTMS. A complete, written or electronically signed, study consent and HIPAA authorization form are required for registration.

STUDY SCHEMA

Review list of breast cancer patients at Fred Hutch and University of Washington for potentially eligible participants

↓

Eligibility Screening

↓

Consent patients (n=40)

↓

Complete baseline survey

↓

Play misinformation escape room game intervention and take part in a debrief

↓

Complete post-intervention survey

6.0 STUDY PROCEDURES AND INTERVENTION

6.1 Recruitment strategies

1) Physician support. Prior to initiating recruitment, physicians seeing breast cancer patients at Fred Hutch will be introduced to the study and it will be requested that their eligible patients be approached for study participation.
2) EPIC reports. We will use EPIC reports to identify patients who meet eligibility criteria. The reports will include the patient's name, age, gender identity, and next appointment details. Once patients are identified, study staff will approach patients in person or contact patients via phone to discuss the study and screen for eligibility.
3) Direct referrals and patient lists from breast cancer clinics. The breast cancer patient lists will be queried to identify potential participants and clinicians will also provide direct referrals. Clinicians can send study staff the names and MRNs of potential patients and/or provide study staff contact information to interested patients. Once patients are identified, study staff will approach patients in person or contact patients via phone to discuss the study and screen for eligibility.
4) Support groups. Study staff will communicate about the study through online patient support groups for breast cancer patients. Study staff will send e-mail messages to support groups. Potential participants will provide the University of Washington team with the following pieces of information: age, breast cancer stage, number of months since diagnosis, demographics.

6.2 Estimated Accrual

Our goal is to consent 40 study participants total (8 groups of n=5). Based on clinic volume and patient flow, we estimate that we can approach and consent n=40 patients within 6 months. On average, in each year of 2020 and 2021, approximately 1,659 new breast cancer patients were diagnosed and treated at Fred Hutch (formerly SCCA), with 1,492 being stage 0-III breast cancer patients. Thus, our proposed recruitment goal is achievable. If a patient drops out prior to the intervention, they will be replaced to reach a final n of =40.

6.3 Consent and Data Collection

If a participant is interested and eligible, study staff will confirm email address and cell phone number. Participants will determine mode of sending communication, either via phone or email.

Table 1 provides information on data collected in this study survey. Please note that some measures map directly on to Study Aims 1 and 2 and other variables are exploratory in nature, as we anticipate the game to influence these variables as well.

Table 1. Survey measures to be collected

	Screening	Baseline	Post -completion of intervention (+ 1 week)
Demographics & clinical characteristics	X	X	
Disease status and treatment		X	X
Behaviors done based on information consumed online (a 6-item background checklist such as “taken over-the-counter medicine)		X	
Aim 1			
Feasibility			X
Acceptability			X
Usability			X
Aim 2			
Types of online information (as measured by 6-item checklist about sources of nutrition information utilized)		X	
Concern about misinformation and confidence in identifying misinformation			X
Cancer nutrition misinformation beliefs (as measured by cancer nutrition beliefs)		X	X
Additional exploratory variables			
Trust and information-seeking		X	X
Vulnerability to misinformation		X	X
Healthy skepticism		X	X
Confidence in and motivation to share information with a medical professional		X	X
Awareness of misinformation		X	X
Exit/debrief questions and interview			
Game enjoyment/recommendation to others			X
Qualitative exit interview			X

Informed Consent

Prior to any data collection, participants will provide written (in person) or electronic informed consent via a HIPPA-compliant and secured REDCap electronic form (eConsenting) for participation in the study and data collection procedures, including release of medical records regarding cancer diagnosis and cancer treatment. Research staff will review the study in detail and outline participant involvement during the screening process in person or remotely (via telephone or video conferencing). Research staff will discuss the consent process with the potential participant prior to providing consent. All items in the informed consent will be discussed, including why the study is being conducted, the number of people participating, what is involved in the study, how long the participant will be in the study, the risks and benefits of the study, alternatives to participation,

confidentiality, rights as a participant, and who to call with questions or concerns. Participants will be encouraged to contact research staff any time they have concerns or questions about the study. Each consent is implemented in person or in REDCap. Once an individual agrees to participate and consent electronically, they will electronically sign the informed consent, then hit submit, and a PDF of the completed consent can be automatically generated and saved to preserve the exact consent text along with the research participant's responses. To make this less burdensome, we will collect patients' doctor/medical institution information as part of the medical release form and our staff can directly contact their doctors to confirm agreement and appropriateness of their participation in the study. This approach will not apply to caregivers or providers involved in this study.

Data Collection
Eligible participants will undergo in person or remote assessments that will include in person, over the phone, video conferencing, and/or web-based data collection.

Data collection will include completion of a written or electronic eConsent form via a secure HIPPA-compliant REDCap survey and the following assessments: (1) Questionnaires assessing demographics, medical history, clinical characteristics (pre- and post-intervention); (2) *Feasibility* will be assessed by rates of accrual to the study; (3) *Acceptability* will be assessed using two Liker-type scales to assess satisfaction (1 = not at all satisfied, 10 = very satisfied) and likelihood to recommend the game to someone else (1 = not at all likely, 5 = very likely) (post-intervention); (4) *Usability* will be assessed with the System Usability Scale (SUS) (post-intervention only), which is a 10-item scale, scored on a 5-point Likert scale (1 = strongly disagree, 5 = strongly agree) (post-intervention); (5) *sources of nutrition information utilized* (6-item checklist) (baseline), (6) *behaviors done based on information consumed online* (6-item checklist) (baseline); (7) *trust and information-seeking* (5-item scale scored on a 7-point Likert scale; 1 = strongly disagree, 7 = strongly agree) (baseline and post-intervention); (8) *vulnerability to misinformation* (3-item scale scored on a 7-point Likert scale; 1 = strongly disagree, 7 = strongly agree) (baseline and post-intervention); (9) *healthy skepticism* (6-item scale scored on a 7-point Likert scale; 1 = strongly disagree, 7 = strongly agree) (baseline and post-intervention); (10) *confidence in sharing and motivation to share information with a medical professional* (2 items from the "Confidence Sharing Information with a Medical Professional" scale scored on a 7-point Likert scale; 1 = not at all confident; 7 = very confident and 2 adapted items to measure degree of motivation; 1 = not at all motivated, 7 = very motivated) (baseline and post-intervention); (11) *Awareness of misinformation* (baseline and post-intervention), (12) *Concern about misinformation and confidence in identifying misinformation* (baseline and post-intervention), (13) *Cancer nutrition information beliefs* (baseline and post-intervention), and (14) brief semi-structured feedback exit interview (post-intervention only).

7.0 PARTICIPANT EVALUATION

7.1 Study Questionnaires and Assessments

- ***Background information***
  - *Demographic and disease characteristics* will include age, gender, race/ethnicity, education level, marital and parental status, income, cancer type, date of diagnosis, and cancer stage.
  - *Behaviors done based on information consumed online* will be assessed with a 6-item checklist asking which behaviors participants have done because of something they saw on the Internet (e.g., "Taken an over-the-counter medicine or supplements, for example, vitamins, minerals, or nutritional supplements").
- ***Aim 1:***
  - *Feasibility* will be assessed by rates of accrual and completion of game sessions.
  - *Acceptability* will be assessed using two Likert-type scales to assess satisfaction (1 = not at all satisfied, 10 = very satisfied) and likelihood to recommend the game to someone else (1 = not at all likely, 5 = very likely).
  - *Usability* will be assessed using the *System Usability Scale (SUS).*[8,9] The SUS is a reliable, 10-item measure 10-item scale, scored on a 5-point Likert scale (1=strongly disagree; 5=strongly agree), with previously reported excellent internal reliability (Cronbach's α = 0.91).
- ***Aim 2:***

- *Types of online information (e.g., sources of nutrition information utilized)* will be assessed using a 6-item checklist that asks which resources participants or their family members have used to find nutrition information in the past 3 months (i.e., a self-care/health and wellness book, a telephone advice service, a booklet/flyer shared by a health professional, Internet forums, Internet search, social media).
- *Concern about misinformation and confidence in identifying misinformation* will be measured using our 4-item scale in which patients indicate degree to which they agree with statements (e.g., "I feel more confident in my ability to identify misinformation"; 1= strongly disagree, 5 = strongly agree).
- *Cancer nutrition information beliefs* will be measured using a 15-item checklist of common cancer nutrition misinformation and credible nutrition advice. Participants rate the items on a 5-point Likert-scale (1= definitely false, 5 = definitely true).

- ***Exploratory outcomes:***
  - *Trust and information-seeking* will be assessed using a validated 5-item measure asking the degree to which individuals trust health information sources (e.g., "I trust the health information I get from my doctor).[10] This scale is rated on a 7-point Likert scale indicating the degree to which individuals agree with each statement (1 = strongly disagree, 7 = strongly agree).
  - *Vulnerability to misinformation* will be assessed using a validated 3-item measure that asks participants the degree to which they believe they or those in their social network are vulnerable to misinformation (e.g., "I am able to identify news or information that misrepresent reality or is even false."[11] Items are rated on a 7-point Likert scale (1 = strongly disagree, 7 = strongly agree).
  - *Healthy skepticism* will be assessed using an adapted version of a validated 6-item measure that measures the degree to which participants are skeptical of online posts (e.g., "I am confident in my assessment of this post as emotionally manipulative/overgeneralizes/doesn't refer to authoritative evidence/cherry picks data").[12] Items are rated on a 7-point Likert scale (1 = strongly disagree, 7 = strongly agree).
  - *Confidence in sharing information with a medical professional* will be assessed using three adapted items from the validated "Confidence Sharing Information with a Medical Professional" scale.[13] Items ask participants the degree to which they are confident or motivated in sharing information with their doctor (e.g., "How confident are you in your ability to ask a doctor for more information if you don't understand what he or she said?"). Items are rated on a 7-point Likert scale (1 = not at all confident, 7 = very confident).
  - *Awareness of misinformation* will be measured using our 5-item scale used in our prior study to assess the degree to which the intervention makes users more aware of misinformation types and common tactics (e.g., emotionally charged language, false data; 1 = not at all aware, 7 = fully aware).
- ***Exit/debrief questions and interview:***
  - *Game enjoyment/recommendation to others* will be measured using an adapted version of a 12-item scale designed to assess how much individuals enjoyed the game and would recommend it to others (e.g., "I felt content").[14] Items are rated on a 5-point Likert scale (0 = not at all, 4 = extremely).
  - Using a *semi-structured feedback debrief interview*, participants will be asked about their experiences with the games to inform future iterations and refinement of the escape room game.

7.2 Semi-structured Qualitative Interview

A brief semi-structured feedback interview will be conducted to gain additional insights and feedback for modifications needed to the intervention to optimize it. Immediately after the escape room session, a nutrition expert will facilitate a 15-20 minute group interview with the participants to give them an opportunity to reflect on their experience with the game. The objective of the semi-structured group interview is to understand how participants' attitudes and feelings about misinformation may have been impacted by the escape room experience. The interview will also explore how vulnerable participants feel to health information and their comfort level with questioning the source and nature of information. The nutrition expert will use a short

interview guide (9 questions) to facilitate the group interview. The role of the facilitator will be to elicit people's opinions and allow others to carry the conversation, making sure the discussion stays on topic and stepping in to provide additional information as a nutritional expert.

8.0 PARTICIPANT WITHDRAWAL

Participants can discontinue participating at any time and for any reason, including during a study interview.

9.0 CONCOMITANT MEDICATIONS

N/A

10.0 ADVERSE EVENTS

10.1 Adverse Event

This is a low-risk, behavioral intervention study. Any adverse events will be recorded in the Adverse Event Summary Form and reported as follows.

10.2 Adverse Event Grading Scale

0 = No Adverse Event or within normal limits.
1 = Mild Severity: Transient laboratory test alterations; discomforts noted but no disruption of daily activities; no therapy, or only symptomatic therapy required.
2 = Moderate Severity: Laboratory test alterations indicating injury without long-term risk; discomfort sufficient to modify normal daily activity; specific therapy required (i.e., more than symptomatic).
3 = Serious Severity: Laboratory test indicating a serious health threat or permanent injury; incapacity, inability to work, inability to perform normal daily activity; hospitalization required or prolonged; emergency treatment required; life-threatening events; death.

Plan for unanticipated AE reporting: All unanticipated AEs related to the study procedures that are severe or serious will be reported by Dr. Megan Shen to the IRB within 10 days of notification of the investigator.

Plan for anticipated AE reporting: All anticipated AEs related to the study procedures will be documented in the study's Reportable Events Log.

Plan for ongoing review of results: The PI will be notified within 24 hours by the research manager of any early terminations due to an adverse event.

Plan for safety review: The PI will perform a cumulative review of all adverse events and premature terminations review every 3 months after study initiation or after completion of 50% of participant visits, whichever occurs first.

Plan for annual reporting: A summary of the investigation including all adverse events and how they were handled, enrollment, drop-outs and reason for discontinuation and any protocol modifications will be provided to the IRB on an annual basis.

Annual Reports will contain:

a. The number of adverse events and an explanation of how each event was handled.
b. The number of complaints and how each complaint was handled.
c. The number of participant withdrawals and an explanation of why the participant withdrew or was withdrawn.
d. The number of protocol deviations and how each was handled.

The occurrence of any serious and unexpected event may prompt changes in study protocol. Any such change will be approved by the IRB before implementation.

10.3 Serious Adverse Event (SAE)

An adverse event should be classified as an SAE if it meets one of the following criteria:

Fatal	Adverse event results in death.
Life threatening:	The adverse events placed the participant at immediate risk of death. This classification did not apply to an adverse event that hypothetically might cause death if it were more severe.
Hospitalization:	It required or prolonged inpatient hospitalization. Hospitalizations for elective medical or surgical procedures or treatments planned before enrollment in the treatment plan or routine check-ups are not SAEs by this criterion. Admission to a palliative unit or hospice care facility is not considered to be a hospitalization.
Disabling/incapacitating	Resulted in a substantial and permanent disruption of the participant's ability to carry out normal life functions.
Congenital anomaly or birth defect:	An adverse outcome in a child or fetus of a participant exposed to the molecule or treatment plan regimen before conception or during pregnancy.
Medically significant:	The adverse event did not meet any of the above criteria but could have jeopardized the participant and might have required medical or surgical intervention to prevent one of the outcomes listed above.

11.0 DATA AND SAFETY MONITORING PLAN

This is a low-risk, behavioral intervention study. To ensure data safety and accuracy, the measures described below will be taken.

Table 2 below describes each data monitoring activity, responsible staff person, and frequency of review. Tracking forms will be developed to document the occurrence of all reviews. The PI will review all reports as they are generated. Study data will be stored on a secure network and the file will be password protected. A file linking participants' names and study ID numbers will be stored separately from the data file. This file will also be stored on a secure network and password protected. Only study staff will have access to these files and the passwords will be changed in the event of study staff turnover.

Table 2. Data monitoring

Activity	Report	Timing of review by PI
Study Recruitment	Weekly report generated by CRC	Weekly PI review
Enrollment	Weekly report generated by CRC	Weekly PI review
Study Retention	Weekly report generated by CRC	Weekly PI review
Informed Consent	Quality control of each new consent	PI reviews all consents upon receipt
Interviews/Self-Report Measures	PI and other study staff will review all interview and self-report materials and complete fidelity checklist	PI will review data weekly for completeness and accurate entry into a spreadsheet for analysis

A data safety and monitoring committee is not needed as this is not a Phase 3 clinical trial. Dr. Megan Shen (PI) will oversee the data safety and monitoring for this project. She will meet with the study staff to discuss protocols and procedures to ensure participant safety and the validity and integrity of the study data. All staff

members will attend trainings on these procedures and will be given information on the importance of reporting any adverse event immediately. Dr. Shen and the IRB will be alerted about any adverse events immediately. Dr. Shen will discuss any adverse effects and examine available data to assess whether safety is compromised. Action to resolve the adverse event will be discussed with IRB prior to implementation. The team will enact any actions recommended by the IRB.

12.0 DATA MANAGEMENT/CONFIDENTIALITY

REDCap
We will use REDCap to track, collect and maintain study data. REDCap is a web-based electronic data capture system. Using the HIPAA-compliant REDCap platform, we will design, build, and maintain the data forms that will be used for data capture, including screening, consenting, participant questionnaires, and staff forms for participant tracking.

13.0 STATISTICAL CONSIDERATIONS

13.1 Study Design
The current study is an open, single-arm trial.

13.2 Analyses
Feasibility, acceptability, and usability will be examined by conducting frequency and descriptive statistics for Likert-scale questions and SUS scale. We will conduct preliminary pre/post analyses using repeated measures analysis of variance (ANOVAs) on the misinformation belief scales to assess changes in these beliefs. Finally, we will conduct qualitative analyses on the open-ended questions using a responsive interviewing model for data coding and analysis in which data units or "blocks of information that are examined together" (p. 202) are combined based on the theme they represent.[15] Trained raters will independently review the transcripts and identify passages that include information on participants' suggestions for modifications to the escape room game. The themes identified in this analysis will inform additional revisions to the intervention as determined by the study investigators.

13.4 Ethnic and Gender Distribution Chart
We will recruit cancer patients who are treated at Fred Hutchinson Cancer Center, which reflect the demographics for the Seattle area and the previously SCCA population. Based on the demographics of the entire SCCA oncology patient population since 2001 (for which data is currently available), 78.6% of cancer patients are female. Patient race/ethnicity distribution in this population are 53.2% White, 10% Asian, 6.8% Black or African Americans, 1.3% Alaskan Indian or Alaskan Native, 1.2% Hispanic, 1.1% other, 0.8% Native Hawaiian or Other Pacific Islander, 0.3% multiracial, and 25.3% unknown. The projected target patient accrual for this study is based on these estimates. Due to this recruiting a breast cancer patient population, we anticipate recruiting female only patients.

Projected Target Accrual
ETHNIC AND GENDER DISTRIBUTION CHART

TARGETED / PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex / Gender		
	Females	Males	Total
Hispanic or Latino	1	0	1
Not Hispanic or Latino	39	0	39
Ethnic Category Total of All Subjects*	40	0	40
Racial Categories			
American Indian / Alaska Native	1	0	1
Asian	4	0	4

Native Hawaiian or Other Pacific Islander	1	0	1
Black or African American	2	0	2
White	32	0	32
More Than One Race	0	0	0
Unknown	0	0	0
Racial Categories: Total of All Subjects*	40	0	40

14.0 INVESTIGATOR OBLIGATIONS

The PI is responsible for the conduct of the study at the site and is responsible for personally overseeing the treatment of all study participants. The PI must assure that all study site personnel, including Co-Investigators and other study staff members, adhere to the study protocol and to all applicable regulations and guidelines regarding proper research protocols both during and after study completion. All participants are informed of the nature of the study, its possible risks, and their right to withdraw at any time, and each participant signs a form indicating their consent to participate prior to engaging in any study-related procedures.

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