Intervening on Women's Health for Rural Young Cancer Survivors

Study Protocol with Statistical Analysis Plan and Informed Consent Form

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Study Protocol

Background

In pursuit of cure, most young female cancer survivors undergo chemotherapy and/or endocrine therapy. Both modalities disrupt normal ovarian function. As a result, young female cancer survivors are at high risk of late effects related to reproductive health: estrogen-deprivation symptoms, infertility, limited contraception options, and sexual dysfunction. These reproductive health issues are highly prevalent and result in poorer quality of life. Clinical practice guidelines recommend that reproductive health risks be addressed through oncofertility care beginning at diagnosis and continuing throughout survivorship. However, delivering individualized reproductive health education in routine oncology practice remains challenging, highlighting the need for scalable educational tools that support guideline-concordant survivorship care.

Survivorship care plans (SCPs) are personalized documents intended to summarize recommended follow-up care to support long-term survivorship management. Despite their widespread use, currently available SCP templates provide limited reproductive health guidance and generally offer broad recommendations rather than treatment-specific information tailored to an individual's cancer history. As a result, survivors may receive generalized information about potential reproductive late effects without clear, actionable guidance regarding their personal risks, recommended surveillance, or available reproductive health services.

To our knowledge, only one reproductive health SCP (RH-SCP) has demonstrated effectiveness in improving the management of reproductive health symptoms in a randomized clinical trial. However, that intervention was evaluated primarily among well-educated, English-speaking, White breast cancer survivors and did not specifically address health literacy, bilingual delivery, or individualized treatment-related reproductive risk communication. Evidence therefore remains limited regarding educational interventions designed for culturally and linguistically diverse young female cancer survivors.

Hence, we were motivated to adapt the RH-SCP for Spanish-speaking Latina young cancer survivors into a web-based educational platform to deliver personalized, bilingual survivorship information in a standardized, scalable format. Additionally, we developed a multi-component reproductive health care intervention that includes a clinic-based reproductive health needs screening and referral to reproductive health patient navigation session with review of the web-based RH-SCP, and telehealth consultation with a reproductive health specialist to address active reproductive health needs.

Study Objective

This study aimed to evaluate the feasibility of a multi-component intervention to improve young female cancer survivors' engagement in goal-concordant reproductive health care. The investigators hypothesized that implementation of the intervention would result in increased young cancer survivors' engagement in goal-concordant reproductive health care.

Study Design

A single arm pilot hybrid type I clinical trial was conducted between December 2024 to September 2025 at a community oncology clinic located in a rural U.S.-Mexico border region.

Study Population
Eligible participants were female cancer survivors aged 15 to 50 years who were English- or Spanish-speaking, resided in Imperial County, California, and were receiving oncology care at the participating clinic.

Intervention
The multi-component reproductive health care intervention included:
1) An oncology clinic-based reproductive health needs screen to assess i) desire to have a child in the future, ii) need for contraception, and iii) sexual health/menopause symptoms.
2) Reproductive health patient navigation with a member of the study team to: i) assess the patient's reproductive health needs, ii) provide individualized patient education and counseling on a) infertility risk related to cancer type and treatment and b) screening and management strategies for reproductive health needs, and iii) provide support with the goal of engaging in goal-concordant reproductive health care.
3) Telehealth reproductive health consultation with a reproductive health specialist to address active reproductive health concerns.

Study Procedures
During routine oncology visits, clinic staff (medical assistants and nursing) completed a brief reproductive health screening with eligible cancer survivors and referred eligible survivors to the research team. Participants who agreed to participate completed electronic informed consent and a baseline questionnaire before attending the reproductive health patient navigation session. Following the navigation session, participants with active reproductive health concerns were offered a telehealth reproductive health consultation with a reproductive specialist.

Primary Outcome
The primary outcome is the proportion of patients' engagement in goal-concordant reproductive health care. Study staff abstracted engagement in goal-concordant reproductive health care from patients' medical records. Engagement in goal-concordant reproductive health care was assigned to patients who underwent: 1) reproductive health needs screen and had no needs, OR 2) reproductive health needs screen, completed a navigation session and received reproductive health counseling and management strategies, and had no further needs; OR 3) reproductive health needs screen, completed a navigation session and received reproductive health counseling and management strategies, had a need, underwent a telehealth reproductive health consultation, and had no reproductive health service needs; OR 4) reproductive health needs screen, completed a navigation session and received reproductive health counseling and management strategies, had a need, underwent a telehealth reproductive health consultation, had a reproductive health service needs, and received appropriate services.

Statistical Analysis Plan
Participant demographic and cancer characteristics and engagement in goal-concordant reproductive health care are summarized using descriptive statistics. Continuous variables are presented as means and standard deviations (SD), whereas categorical variables are reported as frequencies and percentages.

University of California, San Diego
Consent to Act as a Research Subject

Intervening on Women's Health for Rural Young Cancer Survivors

Who is conducting the study, why you have been asked to participate, how you were selected, and what is the approximate number of participants in the study?
Dr. Irene Su, MD, MSCE, and her associates are conducting a research study to find out more about the delivery of women's health care in young women with cancer. You have been asked to participate in this study because you are a young woman who is a cancer survivor. There will be about 50 participants in this study.

Why is this study being done?
The purpose of this study is to determine if a multi-component intervention will improve women's health in young cancer survivors.

What is involved in the study?
If you agree to be in this study, the following will occur:

1. You may be asked to complete a questionnaire about your health and how you feel about strategies for women's health care at enrollment and 8 weeks later.
2. You may be asked to complete a navigation visit with a patient navigator to discuss your women's health needs and review a women's health survivorship care plan.
3. You may be asked to participate in a 1-hour long telephone, Zoom, or in-person interview at which you will provide input on delivery of women's reproductive health care and relevance to young cancer survivors. Each interview will be led by Dr. Su or other trained interviewers.
4. Counseling sessions with your patient navigators and/or doctors may be video or audio recorded with your consent.

The interview and counseling sessions will be audio or video recorded and written out word-for-word. A research team member will review the recording and compare it to the written version to be sure that it is accurate. After the recording is reviewed, the video or audio recording will be destroyed.

How much time will each study procedure take, what is your total time commitment, and how long will the study last?
The navigation visit with take 1 to 2 hours. The interview will take 1 hour. The video or audio recordings of your counseling sessions will be a part of your normal clinical care and will not take additional time. The questionnaire will take about 30 minutes. The study will last about 2 years overall.

What risks are associated with this study?
Participation in this study may involve some added risks or discomforts. These include the following:

1. You may find it uncomfortable talking and answering questions about your cancer and reproductive health experiences. You can choose not to take part in answering any questions that make you uncomfortable. You may also stop the recording at any time.
2. There is also the risk of loss of confidentiality should study information that is personally identifiable be mistakenly released or shared.

Because this is a research study, there may be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

What are the alternatives to participating in this study?
The alternative to participation in this study is not participating in the study.

What benefits can be reasonably expected?
There will not be any direct benefit to you from participating in this study. The investigators, however, may learn more about reproductive health symptoms in young women who have survived cancer.

Can you choose to not participate or withdraw from the study without penalty or loss of benefits?
Participation in research is entirely voluntary. You may refuse to participate or withdraw at any time without penalty or loss of benefits to which you are entitled. If you decide that you no longer wish to continue in this study, please inform the investigators of your wishes by calling Dr. Su at the number provided below in the 'Who can you call if you have questions?' section. You will be told if any important new information is found during the course of this study that may affect your wanting to continue.

Can you be withdrawn from the study without your consent?
You may be withdrawn from the study if you do not follow the instructions given you by the study personnel.

Will you be compensated for participating in this study?
In compensation for your time, you will receive up to $60 in gift cards for participating in this research.

Are there any costs associated with participating in this study?
There will be no cost to you for participating in this study.

What if you are injured as a direct result of being in this study?
If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the UCSD Office of IRB Administration at (858) 246-4777 for more information about this, to inquire about your rights as a research subject or to report research-related problems.

What about confidentiality?
Research records will be kept confidential to the extent allowed by law. We will keep all research records related to this project in locked files or computer files that can be opened only with a password. We will store names and personal information separately from research records. Study data will be stored in the office of Dr. Su at UCSD and/or at the office of Helen Palomino at the Cancer Resource Center of the Desert. Research records may be reviewed by the UCSD Institutional Review Board, the Moores Cancer Center Data Safety Monitoring Board and Quality Assurance audit staff. Published research results will only describe groups of participants. If we use a quote from a participant, it will only be linked to a general description, such as "cancer survivor, age 22 at diagnosis". We will never use your name or any information that could identify you personally in research journals or other reports.

Who can you call if you have questions?
Dr. Irene Su, Helen Palomino, and/or _____ has explained this study to you and answered your questions. If you have other questions or research-related problems, you may reach Dr. Su by paging her through the UCSD operator at 619-543-6222 or Helen Palomino at 760-353-6571.

You may call the UCSD Office of IRB Administration at (858) 246-4777 to inquire about your rights as a research subject or to report research-related problems.

Please select one option below if you are willing to be contacted for future cancer and reproduction-related studies in young women:

_____You agree to be contacted for future studies.

_____You do not agree to be contacted for future studies

Your Signature and Consent/Assent
You have received a copy of this consent/assent document.

You agree to participate.

_____ _____
Subject's signature Date

Experimental Participant's Bill of Rights

Every individual asked to participate in a research study has the right to be:

1. Informed about the nature and purpose of the study.

2. Provided an explanation of the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. Given a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. Informed about any benefits that would reasonably be expected from the participation in the study, if applicable.

5. Informed about of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. Told of the types of medical treatment, if any, available if complications should arise.

7. Provided an opportunity to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. Informed that individuals can refuse to participate in the research study. Participation is voluntary. Research participants may refuse to answer any question or discontinue their involvement at any time without penalty or loss of benefits to which they might otherwise be entitled. Their decision will not affect their right to receive the care they would receive if they were not in the experiment.

9. Provided a copy of the signed and dated written consent form and a copy of this form.

10. Given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study contact the researchers listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research participant, please contact:

- UC San Diego Office of IRB Administration at irb@ucsd.edu or 858-246-4777