Implementation of a Nurse-Led Program to Decrease Sexual Dysfunction among Gynecological Cancer Survivors
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Dr. Manal Alatrash, PhD, RN, Associate Professor CSUF
Co-Principal Investigator: Corina Hernandez, RN, MSN, ANP-BC
Cedars-Sinai

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Collaborating Institutions and Researchers	CSMC Mentor: Dr. Leah Spiro California State California State University Fullerton (CSUF)-Doctor of Nursing Practice (DNP) CSUF Team Lead: Dr. Manal Alatrash, PhD, RN, Associate Professor CSUF Team Member: Dr. Laura Sarff, DNP, RN, MBA, CPHQ, NEA-BC, Part Time Lecturer

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1.0 Protocol Summary

Study Purpose	• **Patient Cohort** • The purpose of the research is to implement and evaluate a nurse-led clinical program designed to improve screening, referral, and treatment for sexual dysfunction in gynecological cancer patients. • **Nurse Cohort** • The purpose of the research is to increase knowledge and confidence in sexual dysfunction screening, referral and treatment among gynecologic cancer nurses.
Research Procedures	**The primary research procedures are:** • **Patient Cohort** • Assess effectiveness of the nurse led clinical sexual dysfunction program via number of referrals and treatments in the chart before and after the intervention in gynecologic cancer patients. • Assess improvement in sexual dysfunction in gynecologic cancer survivors via the Female Sexual Function Index (FSFI). • **Nurse Cohort** • Increase gynecologic nurses' knowledge and confidence of sexual dysfunction screening, referral and treatment using the Knowledge, Attitude, and Practice Survey in Healthcare (KAP), and the Evidence Based Nursing Practice Self-Efficacy Scale (EPSE).
Subject Population	• **Patient Cohort** • The study will enroll gynecological cancer patients who have completed treatment within the past twelve months. • **Nurse Cohort** • The study will enroll gynecologic oncology nurses in an outpatient comprehensive cancer center
Duration of Subject's Participation	• **Patient Cohort** • The study involves participation of patient subjects at multiple time points. • The total patient study participation is 12 weeks. • **Nurse Cohort** • The study includes the participation of nurse subjects at two time points: pre and post education of sexual dysfunction screening and treatment.

	• The total study duration is 2 hours. Nurses will have 4 weeks to complete the 2 hours.

2.0 Background, Rationale

- Sexual dysfunction (SD) is a common issue among female cancer survivors, profoundly affecting their quality of life (Sousa Rodrigues-Guedes et al., 2022). Sexual dysfunction is highly prevalent among gynecological oncology patients, with rates reaching up to 90% (Kaufman et al., 2024).
- Discussion about sexual dysfunction between patients and healthcare providers are often limited, with reports indicating that such conversations occur in as few as 27.9% of cases (Sousa Rodrigues-Guedes et al., 2022). Several barriers contribute to this communication gap, including healthcare providers feeling unqualified or unprepared, facing time constraints, lacking referral resources, possessing limited knowledge, and being unsure how to broach the topic (Chou et al., 2023; Kaufman et al., 2024; Trachtenberg et al., 2019).
- Unaddressed sexual dysfunction can contribute to psychological distress, which in turn is associated with higher cancer incidence, increased cancer-specific mortality, and worsened survival outcomes (Wang et al., 2020).
- Sexual dysfunction negatively impacts mental, emotional, and relational well-being, contributing to lower HRQOL, an important predictor of morbidity and all-cause mortality in cancer survivors (DuMontier et al., 2018; Sitlinger & Zafar, 2019).
- Depression and anxiety linked to untreated sexual dysfunction can lead to higher emergency department use, longer hospital stays, and healthcare costs that are nearly double those of patients without these conditions (Birch et al., 2023; Masbach et al., 2020).
- Many interventions for sexual health have been investigated. These include psychoeducational and psychotherapeutic interventions, exercise programs, hormone replacement therapy administration, pelvic floor physical therapy, and health provider and patient education (Sopfe et al., 2021).
- There has been success in nurse-led rehabilitation programs that focus on a multi-modal approach to sexual dysfunction in gynecological cancer survivors (Chow et al., 2023; Seaborne et al., 2021; Hungr et al., 2020).

3.0 Study Purpose and Objectives

Patient Cohort

The primary objectives of this study are to implement and evaluate the effectiveness of a nurse led clinical program to improve sexual dysfunction among gynecological cancer survivors. The patient's outcomes will be measured via the Female Sexual Function Index (FSFI).

Nurse Cohort

The secondary objectives of this study are to improve gynecologic cancer nurses' knowledge and confidence in the topic of sexual dysfunction screening, treatment, and referral using the Knowledge, Attitude, and Practice Survey in Healthcare (KAP), and the Evidence Based Nursing Practice Self-Efficacy Scale (EPSE).

4.0 Study Population

4.1 Inclusion Criteria

Patient Cohort

- Patients with a gynecologic cancer history
- Patients ages 30-65 years old
- Patients must have completed cancer treatment within the past 12 months
- Patients may be on maintenance therapy

Nurse Cohort

- Registered Nurses 18 years or older
- Registered Nurses working in the gynecologic clinic in the outpatient cancer center

4.2 Exclusion Criteria

Patient Cohort

- Any records flagged "break the glass" or "research opt-out."
- Patients with severe psychiatric disorders that would impair consent or participation
- Patients with neurological disorders affecting sexual function
- Patients with a history of sexual violence or sexual assault

Nurse Cohort

- Certified Nursing Assistants

4.3 Subject Identification, Recruitment, and Consent

Subjects will be initially identified in the following ways:

Patient Cohort

- The study patient population will be identified from an outpatient cancer center.
- Subjects will be identified through chart audits of patients scheduled to come into clinic who meet the inclusion criteria.

Nurse Cohort

- Registered Nurse subjects will be recruited via email, and weekly staff huddles. Emails will be sent via general email to gynecology oncology nurses and not directly to individual subjects.

4.3.1 Consent Description

Patient Cohort

APP/Co-PI, Corina Hernandez, will identify patients via medical records. Potential participants will be contacted directly by APP/Co-PI through an IRB-approved email message based on the HRP-661 Direct to Patient Recruitment Letter. The patient will be given the opportunity to decline to be contacted, as indicated in the email. The APP/Co-PI will give the patient a reasonable amount of time to agree to or decline to be contacted after the email is sent. If the patient has already been approached by a treating physician about participation in this study, or if the patient has been sent the recruitment letter and has not declined to be contacted, the APP/Co-PI will reach out to the by phone. In the first conversation with the potential participant, the APP/Co-PI will explain the study carefully by going through the consent form via telephone script. The patient will be given the option to decline or defer participation, or, if interested, to sign the ICF by electronic signature via Docusign. The APP/Co-PI will send the potential participant the DocuSign link to the electronic consent form. Those who prefer to complete the consent form in person will have the option to do so electronically on a tablet or on paper. Patients will be highly encouraged to follow up with the study team before signing should they have any additional questions. If the patient indicates they plan to sign the consent form, the APP/Co-PI will follow up with another phone call if necessary to answer any remaining questions. All patients who participate will receive a surveillance visit with an additional focus on sexual health component with the Advanced Practice Provider (Corina Hernandez). However, only patients who complete the pre-and post-FSFI survey and complete the APP visit will be involved in the study. The FSFI survey will be submitted to the patient and completed via REDcap.

Nurse Cohort

Information sheet will be given to nurses using REDcap. Nurses will be recruited to participate in the electronic pre and or post survey and informed they may self-select to participate in the project by clicking the survey link and QR code provided to them. A waiver of documentation of informed consent is being requested. By clicking the link, this implies their consent to participate. Nurses will be informed that they may withdraw from participating in the project at any time by exiting the survey. All nurses in the Gynecology Oncology Outpatient Cancer Clinic will receive Sexual Dysfunction training. However, only nurses who agree/consent to the pre-and post-education surveys (KAP & EBPSE) will be involved in the survey.

5.0 Study Design and Procedures

5.1 Schedule of Events:

Procedures	Screening Period	Visit #1	Telephone Call	8-10 weeks after Visit #1
Informed Consent	R			
FSFI Survey	R			
Medical History		S		
Medication History		S	R	
Pelvic Exam		S		
Focused Sexual Health Questions		S		
Sexual Health Plan of Care, Education, and Referrals		S		
FSFI Survey				R

5.2 Study Design and Duration

Patient Cohort

The study design is an evidence-based practice (EBP) study and includes the implementation and evaluation of a nurse led sexual health clinical program via the FSFI survey. The duration of study participation is 12 weeks. The goal for patients is to have 80% of participating patients to complete pre and post surveys and APP visit as part of their sexual health clinical program, with 30% of patients reporting improvement in sexual dysfunction via the FSFI score.

Nurse Cohort

The study design is an EBP study and includes two surveys in the Registered Nurse participants that includes KAP and EPBSE. The duration of study participation is 4 weeks. The goal is to have 100% of the gynecology oncology registered nurses to participate in the survey and sexual dysfunction education.

5.3 Description of Study Procedures

Patient Cohort

The study involves the participation of patients at multiple time points. The study procedures will assess the patients sexual function using the FSFI prior to the APP sexual health visit and post APP sexual health visit and telephone follow up call. Patients will be recruited through clinical chart identification.

Nurse Cohort

This study involves the participation of registered nurses at multiple time points. The study procedures will assess the nurses' knowledge and confidence using the KAP and EPSE survey before sexual health program and again post education at the end of the study. The survey results will remain anonymous for both the pre and post-test. Nurse subjects will be recruited via email, and staff weekly huddles to complete both surveys.

Medical Record/Clinical Record Review:

Patient Cohort

This study involves review of medical records of patients included in this study. The questionnaire will be administered once at baseline (prior to the APP visit) and at the end of the study (after the telephone follow up call performed 8-10 weeks post APP visit). The study will collect sensitive information. This information is routinely collected per standard of care as as part of clinical care on a regular basis. A study code will be included on the questionnaire. The questionnaire will not be linked to each other and will be administered at two different time points.

- Female Sexual Function Index (FSFI)
    - The FSFI is a validated tool that addresses five domains: desire, subjective arousal, lubrication, orgasm, satisfaction, and pain/discomfort. It encompasses nineteen self-measurement items that provides a score on overall levels of sexual function (Meston et al., 2020).
- Chart review to count the number of referrals and treatments for sexual dysfunction before and after the nurse led sexual health clinical program intervention

Nurse Cohort- N/A

Education:

Nurse Cohort

- The educational content will come from the After Cancer Solutions for Sexual Health Program, a non-profit developed with input from a cancer survivor and specialists to provide evidence-based education for providers and patients (After Cancer, 2025). The program, including the "About Us" pilot and "30 Second Message Workshop," is active across Iowa and aims to normalize sexual health discussions, build provider confidence, and guide appropriate referrals (After Cancer, 2025).
    - 30 second message workshop
    - Access to "About Us" sexual dysfunction patient and provider handouts
    - National Comprehensive Cancer Network Sexual Health Guidelines

Questionnaires/Surveys:

Patient Cohort:

We will be doing the following questionnaires for patient participants:

- *Female Sexual Function Index (FSFI)*
    - The FSFI is a validated tool that addresses five domains: desire, subjective arousal, lubrication, orgasm, satisfaction, and pain/discomfort. It encompasses nineteen self-measurement items that provides a score on overall levels of sexual function (Meston et al., 2020).

Nurse Cohort:

We will be doing the following questionnaires for nurse participants:

- Knowledge, Attitude, and Practice Survey in Healthcare (KAP), and the Evidence Based Nursing Practice Self-Efficacy Scale (EPSE).
    - The questionnaire is not available in languages other than English.
    - The KAP survey is a validated tool that assess knowledge and attitudes about a specific health topic, to identify areas where education efforts need to be applied (Andrade et al., 2020).
    - The EBPSE survey is a validated tool which assesses and monitors nurses' confidence in their ability to implement evidence-based practice (EBP) skills (Tucker et al., 2009).

The study will be conducted at one site only, Cedars-Sinai.

6.0 Data Collection and Management

6.1 Data Procurement

- **Identification/Access/Abstraction**
    - ☒ Members of the study team will require access to the clinical data source (e.g., electronic medical record) to identify eligible data/specimens and to conduct data abstraction or gain access to specimens.[1]
    - ☒ Electronic Information Systems (EIS) Department will identify and/or abstract applicable data or specimens (e.g., RISCC website, request query of Deep6 through EIS).
    - ☐ Separate registry or repository will identify, abstract, and/or provide specimens and/or data to the study team.
    - ☐ Other:

- **Source(s) of Data/Specimens**:

[1] Clinical records can only be accessed by study team members who are listed on the CS-IRB application and are IRB Certified.

- The source(s) of the patient data to be identified are from the patient's medical record. Patient data will be analyzed from the FSFI survey.
- The source(s) of the nurse's data to be analyzed from the KAP and EBPSE survey.

6.2 Time Period of Data under Review

- Data will be collected from/at the following time points: 1-2 times a week from September 2025 to April 2026.
- Information will be kept for no longer than 1 year.

6.3 Data Elements

- The following data points will be collected:
- The following data points will be collected from patients:
  - Age
  - Gender
  - Race
  - Marital Status
  - Gender Identity
  - Sexual orientation
  - MRN
  - Preferred language
  - Medical history
  - Hospital Diagnosis
  - Date of surgery
  - Date of chemotherapy
  - Date of radiation
- If applicable the following data points will also be collected from patients
  - Prior reports of sexual dysfunction
  - Referrals and visits with Pelvic floor physical therapists, Physical Rehabilitation, Genitourinary team, Social Work, and Psychology teams.
- The following data points will be collected from nurses:
  - Age
  - Gender
  - Current work unit
  - Current position
  - Length of time in their current position

The information to be accessed and reviewed is that which is minimally necessary to achieve the goals of this research.

HIPAA Identifiers

☐ **No HIPAA Identifiers will be collected for this study (or select the identifiers from the following list).** *The investigators will not attempt to re-identify subjects from the collected data.*
☒ Medical Record Number
☐ Name
☐ Address (all geographic sub-divisions smaller than state, including street address, city county, and zip code)
☒ All elements (except years) of dates (including birthdate, admission date, discharge date, date of death, and exact age if over 89)
☐ Telephone Numbers
☐ Fax Numbers
☒ Email Address
☐ Social Security Number
☐ Health plan beneficiary number
☐ Account Number
☐ Certificate or license number
☐ Vehicle identifiers and serial numbers, including license plate numbers
☐ Device identifiers and serial numbers
☐ Web URL
☐ Internet Protocol (IP) Address
☐ Finger or Voice Print
☐ Photographic Image (photographic images are not limited to the face)
☐ Any other characteristic that could uniquely identify the individual

6.4 Confidentiality and Security of Data

- **Secure Storage**: Data will be housed in a HIPAA-compliant secure storage system, like REDCap or Box, within the Cedars-Sinai network with access restricted to approved members of the research team.
- **Limited Access:** Private identifiable information will be accessible only to IRB approved study team members with current IRB training.
- **Unique ID Numbers and Coding:** Each patient will be assigned a unique ID number. The linking list will be kept secure. Direct identifiers listed in section 8 will be separated from the study materials (data and/or specimens) as soon as possible. During data abstraction, name and/or MRN are required for data verification purposes. After data abstraction is complete and data have been verified, the name will be removed (if collected). Only the MRN will be used to link the study ID/code to the individual after that point until the linking list is destroyed.
- **Destroying Identifiers:** The identifiers and the linking list will be destroyed as soon as scientifically possible and maintained only as long as necessary to abstract, analyze and verify data.

- **Storage of Physical Records:** Physical records will be maintained for this study at a secure location where access is limited to approved personnel. The records will not be removed from Cedars-Sinai premises.
- **Retention/Destruction of Study Materials:** Study data/materials will be kept and/or destroyed according to applicable policy.
- **Sharing Data:** One or more investigators with access to non-identifiable data are not at Cedars-Sinai. They will be an advisor to the project and assist with data analysis.

Patient Cohort

- The data that will be shared with the collaborating institution/research will include patient information as follows: patient's age, gender, race, marital status, medical history, hospital Diagnosis, date of treatment, date of surgery, date of radiation, prior reports of sexual dysfunction, and prior referrals. The collaborating institution will assist with analyzing the data, writing up the project and results, and disseminating the results.

Nurse Cohort

- The data that will be shared with the collaborating institution/researchers will include nurse KAP and EBPSE survey results, and nurse age, gender, current work unit, current position, and length of time in their current position. The collaborating institution will assist with analyzing the data, writing up the project and results, and disseminating the results.

7.0 Data and Safety Monitoring

7.1 Data and Safety Monitoring Plan

The study will be monitored by the PI to ensure appropriate study conduct, including obtaining proper access to data/specimens, compliance with the HIPAA Privacy Rule, compliance with Cedars-Sinai policy, and adhering to the plans outlined in the protocol for all study procedures, abstracting and recording data, data and/or specimen security and maintenance, and data accuracy and integrity. Any adverse events, deviations, protocol exception requests, potential unanticipated problems involving risks to subjects or others, or other events will be submitted to the IRB in accordance with IRB reporting policy. All study procedures will be conducted in accordance with standard clinical practice.

7.2 Quality Control and Quality Assurance

When PI/study team conducts QC/QA: The PI will delegate a study team member to Corina Hernandez to conduct QC/QA activities. Data will be evaluated for adherence with the protocol and for accuracy in relation to source documents.

8.0 Sample Size and Statistical Considerations

8.1 Sample Size

- This is a single-site study at Cedars-Sinai.

Patient Cohort

- The sample size of the study will vary between patient subjects.
- The patient data will depend on the number of Gynecological Oncology patients in the outpatient cancer center who have completed treatment in the past 12 months. The goal is to recruit 35 patient participants with 80% completing the pre survey, APP visit, and post survey. Goal of 30% participating patients to report improvement in sexual dysfunction via the FSFI.

Nurse Cohort

- The sample size of the study will vary between nurse subjects.
- The goal for nurse participants is to have 100% gynecological oncology outpatient registered nurses' participation in the pre surveys, sexual health education program, and post surveys.

8.2 Statistical Sample Size Justification

A statistical sample size is not required because this study involves:

- A pilot study with at most five nurse participants'
- A pilot study with at most 35 patient subjects

☐Waiver of a sample size justification from the IRB requested due to the following:

- This is an evidence-based practice (EBP) project to inform practice change, not generate generalizable knowledge.
- The sample size is based on the available population within a limited timeframe.

8.3 Statistical Analysis Methodologies

Patient Cohort

- This pilot study will obtain estimates of the following parameters:
- The patient subjects will be, at most, 35 subjects due to the available population and limited timeframe.

- In this survey/questionnaire study, we will assess patients' sexual function in aggregate form.
- The FSFI addresses five domains to include desire and subjective arousal, lubrication, orgasm, satisfaction, and pain/discomfort. It encompasses nineteen self-measurement items that provides a score on overall levels of sexual function (Meston et al., 2020). A Likert scale is used from 1 to 5, with higher scores indicating greater levels of sexual function on the specific item. FSFI is scored in two ways; individual domains and total FSFI score by taking a sum of all scores (Meston et al., 2020).
- We hypothesize that 30% of participants have an improvement in FSFI scores indicated by a ½ standard deviation.
- The project will utilize both QI Macros and Intellectus Statistics to measure the changes in patient sexual function. The analysis will incorporate statistical methods such as run charts, control charts, and t-tests to assess sexual function in patients before and after the intervention. More specifically regarding t-tests with the FSFI tool, we will compare pre and post intervention using paired t-tests.

Nurse Cohort

- The nurse subjects will be at most five.
- In this survey/questionnaire study, we will assess nurses' responses in aggregate form. The KAP survey is comprised of 24 items, each assessed using a 4-point likert scale (Xie et al., 2023).
- Participants evaluate their knowledge and skills on a scale ranging from 1 (inadequate) to 4 (more than adequate). Similarly, they rate the frequency of their practice for each item, from 1 (never) to 4 (almost always). Scores for each subscale, knowledge, attitudes, and practices, range from 24 to 96 (Xie et al., 2023). The total score for the KAP survey is obtained by summing the scores across all subscales, with higher scores indicating greater levels of knowledge, more positive attitudes, and more consistent practices (Xie et al., 2023).
- We hypothesize that 50% of nurses have an increase in KAP scores indicated by a ½ standard deviation.
- In the next survey, EBPSE, we will assess nurses' responses in aggregate form. The EBPSE survey is comprised of 17 items designed to help nurse process information and develop essential EBP skills. Each item is rated on how confident one can perform the activity with percentage numbers 0-100 likert scale (Tucker et al., 2009).
- We hypothesize that 50% of nurses have an increase in EBPSE scores indicated by a ½ standard deviation.
- The project will utilize both QI Macros and Intellectus Statistics to measure the changes in nurses' knowledge and self-efficacy. The analysis will incorporate statistical methods such as run charts, control charts, and t-tests to evaluate changes in participants' knowledge and self-efficacy. More specifically regarding t-tests, the EBPSE will use a paired sample t-test, and the KAP survey will use t-tests to compare pre and post survey responses.

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