Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

Investigating the effectiveness of the continuous care model on quality of life, sexual function and sexual satisfaction of bladder cancer patients undergoing tumor removal surgery

Protocol summary

Study aim
Determining the effectiveness of the continuous care model on improving the quality of life, performance and sexual satisfaction of patients with bladder cancer undergoing tumor removal surgery

Design
A clinical trial with a control group, with parallel groups, without blinding, non-randomized, will be conducted on 57 patients.

Settings and conduct
The research will be conducted in Labafinejad, Imam Hossein and Shahada Tajrish hospitals under the supervision of Shahid Beheshti University of Medical Sciences.

Participants/Inclusion and exclusion criteria
Patients including both sexes and in the age range above 18, not performing two or more simultaneous surgeries, having a sexual partner ; Failure to complete the care period, patients with previous sexual disorders, patient deterioration and patient death

Intervention groups
The intervention group: According to the continuous care model, in four stages of familiarization, sensitization, control and evaluation in patients with bladder cancer undergoing surgery, care and education regarding familiarity with the disease, the importance of performing permitted physical activity, the importance of quitting smoking, how to perform dressings, and teaching proper sexual positions regard to the surgery will be done. Questionnaires of sexual satisfaction, quality of life, women's sexual function and erectile dysfunction will be completed at the beginning, two weeks after surgery and three months after the intervention. This care will continue for three months and then the results will be analyzed. The control group: In this group, the center's routine nursing care will be performed by the staff for the patient. At first, one week and three months after the re-discharge, the questionnaires will be provided to the patients for completion.

Main outcome variables
improving the quality of life; improving sexual performance; Enhance sexual satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240221061076N1**
Registration date: **2024-03-02, 1402/12/12**
Registration timing: **registered_while_recruiting**

Last update: **2024-03-02, 1402/12/12**
Update count: **0**

Registration date
2024-03-02, 1402/12/12

Registrant information

Name
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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-03-02, 1402/12/12

Expected recruitment end date

2024-09-21, 1403/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of the continuous care model on quality of life, sexual function and sexual satisfaction of bladder cancer patients undergoing tumor removal surgery

Public title

the effectiveness of the continuous care model in patients with bladder cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The patients include both men and women and are over 18 years of age. Patients have not performed two or more surgeries at the same time. Patients have sexual partners.

Exclusion criteria:

Failure to complete the care period Patients with previous sexual disorders based on the diagnosis of the attending physician Deterioration of the patient's condition, death of the patient, lack of access of the researcher to the samples, or any condition that makes it impossible for the samples to participate in the research.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee in research of pharmacy, nursing and midwifery faculties of Shahid Beheshti Univers

Street address

Faculty of Nursing and Midwifery, in front of Shahid Rajaei Heart Hospital, Hashemi Rafsanjani Blvd, Vali Asr St

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Province

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Postal code

1996835119

Approval date

2024-02-12, 1402/11/23

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1402.264

Health conditions studied

1

Description of health condition studied

Bladder Cancer

ICD-10 code

D09.0

ICD-10 code description

Carcinoma in situ of bladder

Primary outcomes

1

Description

Quality of Life

Timepoint

At the beginning of the study (before the start of the intervention), two weeks after surgery, three months after the intervention

Method of measurement

Aaronson quality of life questionnaire for cancer patients

2

Description

sexual satisfaction

Timepoint

At the beginning of the study (before the start of the intervention), two weeks after surgery, three months after the intervention

Method of measurement

Larson sexual satisfaction questionnaire

3

Description

Male sexual function

Timepoint

At the beginning of the study (before the start of the intervention), two weeks after surgery, three months

after the intervention

Method of measurement

Questionnaire of the International Index of Erectile Function

4

Description

Women's sexual performance

Timepoint

At the beginning of the study (before the start of the intervention), two weeks after surgery, three months after the intervention

Method of measurement

Rozen Women's Sexual Performance Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: 1. In the familiarization phase, the first session will be held during a 30-40 minute session with the presence of the patient and his family. This step will be done the day before the patient's surgery (when the patient is admitted to the hospital for the first time). At this stage, the researcher, the patient and his family will get to know each other and express their expectations and emphasize the necessity of not interrupting the care relationship. The actions of this stage of the intervention include introducing the nurse to the patient and the family and completing the checklist of demographic status, quality of life, sexual satisfaction, women's sexual function and erectile dysfunction, clarifying the expectations of the patient and his family, completing the informed consent form, determining the agreement on times Face-to-face, telephone and virtual meetings and how communication is possible. 2. In the sensitization phase, according to the follow-up care model, the next meeting will be held in order to sensitize and involve the patient and family in the matter of care and follow-up, which will be held at the place of the research (hospital) and with prior coordination with the patients and their families. It will take 90 to 120 minutes to examine and pay attention to the care axes and all educational-care needs of the patients. This step will be done two days after surgery. The content of the educational program will be adjusted based on the latest articles and books and consultation with expert professors. The purpose of this stage is to teach information related to the familiarity with the disease, the nature of bladder cancer and tumor removal surgeries as far as the patient and their family understand, the importance of following the medication regimen, the importance of performing permitted physical activity, the importance of quitting smoking, how to perform dressings and Wound care, the need to reduce stress and mental pressure and ways to overcome it, teaching proper sexual positions and teaching how to have sex are performed with attention to surgery. This session will be conducted as face-to-face training. The mentioned interventions are during the hospitalization of the patients in the hospital and continue at home after discharge. At the end of the session, the educational package including self-care booklets will be provided to the patients and their families. This stage will only take place in the intervention group. 3. In the control phase, the goal of this phase is to continue the process of implementing the follow-up care model, because the most suitable programs without control and follow-up will be forgotten with the passage of time. A week after discharge, questionnaires on sexual satisfaction, quality of life, women's sexual performance and erectile dysfunction will be taken again. The continuous follow-up of patients after discharge from the hospital is based on the educational and self-care needs of the patients, and the researcher agrees with the patients and their families that after discharge and at home they encountered any problems and questions through phone calls, video calls or Seek solutions by sending messages in cyberspace. For 3 months, follow-up care in the form of phone calls, video and virtual pages (messages, videos and training photos will also be sent in this way) according to care needs, frequently with the aim of checking the care process and how They, checking and paying attention to care issues and problems are implemented. 4. The evaluation stage is proposed as the final step of follow-up care, but it will be taken into account and current in all stages, and finally, after 3 months of the implementation of the collection model, the collection model of the quality of life and sexual satisfaction questionnaires will be completed again by the patients. became. The data will be analyzed using statistical tests.

Category

Rehabilitation

2

Description

Control group: Control group: In this group, the familiarization phase will be carried out in the same way as the intervention group, but it is different from the point of view of time and the type of expectations of the next programs. Because the purpose of familiarization for the control group is to encourage them to cooperate and complete the desired data. At this stage, questionnaires on sexual satisfaction, quality of life, women's sexual performance and erectile dysfunction will be completed. The center's routine nursing care including taking vital signs, how to change dressings, post-surgery care, how to take medicines and the amount of activity allowed will be explained to the patient by the staff. Patients' numbers will be taken and a week after discharge, questionnaires on sexual satisfaction, quality of life, women's sexual performance and erectile dysfunction will be provided to patients for completion. In the meantime, no training will be given to the patients and only questionnaires will be given to the patients to complete. At the end of three months, the questionnaires will be provided to the patients for completion. After the end of the internship, flowcharts

and educational resources will be provided to the patients.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Labafinejad hospital

Full name of responsible person
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2

Recruitment center

Name of recruitment center
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3

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Beheshti University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Fateme Rezaeeniya

Position
Master student

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available