Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

The effect of the motion exercise program on the quality of life in prostate cancer survivors

Protocol summary

Study aim

Determine the effect of exercise program on the quality of life of survivors of prostate cancer

Design

In this study, survivors of prostate cancer who had a medical record in the center of radiotherapy at Imam Khomeini Hospital in Tehran and had criteria for entering the study, were the sample of the study. Patients with selected entry criteria were selected by random sampling method. A random sample of 80 people entered the study and randomly divided into intervention and control groups. To conceal the intervention group, each participant had a code is assigned.

Settings and conduct

Patients in the intervention group were divided into 5 groups of 8, according to their area of living and their convenient access to sports facilities in the park near the place of residence. At first, the benefits of physical activity and how the exercise program was performed during the research period by the researcher was taught to the participants in each of the 5 groups and a exercise program was provided to them. Regarding the coordination with the municipality of Tehran, the patients in the intervention group during the study, which lasted for 12 weeks, performed one weekly session in a group under the supervision of a researcher in the park's physical environment and three sessions per week individually. Aerobic walking was performed in walking style with mild to moderate intensity (based on patient tolerance). Resistive exercise movements were performed for muscle strength with mild to moderate intensity (based on patient tolerance) for each large muscle group twice a week, once grouped. Stretching exercises for pulling of the main muscles and tendons were also done twice a week in a single session, individually and one session. In addition, patients with urinary incontinence were trained and recommended for pelvic floor exercise، Which performs these movements daily. Questionnaires related to quality of life were completed before and after the intervention in both control and intervention groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients diagnosed with prostate cancer and completed active treatment within 3 to 12 months The absence of metastasis to other locations The absence of neurological, cardiovascular, respiratory or any disorder that prevents physical activity. At least 45 years of age exclusion criteria: Changes in health condition that prevent physical activity

Intervention groups

In this study there is an intervention group that carries out exercise exercises. And there is a control group that there will be no action or intervention in this group.

Main outcome variables

quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180113038347N1**
Registration date: **2018-01-23, 1396/11/03**
Registration timing: **retrospective**

Last update: **2018-01-23, 1396/11/03**
Update count: **0**

Registration date

2018-01-23, 1396/11/03

Registrant information

Name

Abbas Mardani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-05-21, 1396/02/31
Expected recruitment end date
2017-10-21, 1396/07/29
Actual recruitment start date
2017-05-21, 1396/02/31
Actual recruitment end date
2017-12-20, 1396/09/29
Trial completion date
empty

Scientific title
The effect of the motion exercise program on the quality of life in prostate cancer survivors

Public title
"The effect of the motion exercise program on the quality of life in prostate cancer survivors"
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Patients diagnosed with prostate cancer and completed active treatment within the past 3 to12 months Lack of metastasis The absence of neurological, cardiovascular, respiratory or any other problems that prevent physical activity At least 45 years of age Conscious consent to participate in the study Residence in Tehran
Exclusion criteria:
Absent more than three sessions in group exercise sessions Changes in health condition that prevent physical activity
Age
From **45 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Actual sample size reached: **71**
Randomization (investigator's opinion)
Randomized
Randomization description
The method of sampling in this research is simple random sampling using random numbers table. In this way, patients with prostate cancer who have criteria for entering the study are selected, then each patient is given a code and using the random numbers table, the first code is equal or smaller than the number of patients eligible for the study Enter the control group and one in each patient according to the code assigned to the intervention and control group, and to some extent in the random numbers table we go to each of the intervention and control groups of 40 patients.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی تهران
Street address
Tehran University of Medical Sciences, Nursing and Midwifery Faculty, Tehran, Iran
City
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Postal code
1419733171
Approval date
2017-05-02, 1396/02/12
Ethics committee reference number
IR.TUMS.FNM.REC.1396.2209

Health conditions studied

1

Description of health condition studied
Prostate Cancer Survivors
ICD-10 code
C61
ICD-10 code description
Malignant neoplasm of prostate

Primary outcomes

1

Description
Quality of Life
Timepoint
At the beginning of the study (before the intervention) and after the end of the intervention (duration of intervention 12 weeks)
Method of measurement
Using EORTC QLQ-C30 Quality of Life Questionnaire. V 3 and EORTC QLQ-PR25 belonging to the European Cancer Research & Treatment Organization.These two complementary questionnaires are also used to measure the quality of life of patients with prostate cancer.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention group were divided into 5 groups of 8, according to their area of living and their convenient access to sports facilities in the park near the place of residence. At first, the benefits of physical activity and how the exercise program was performed during the research period by the researcher was taught to the participants in each of the 5 groups and a motor exercise program was provided to them. Regarding the coordination with the municipality of Tehran, the patients in the intervention group during the study, which lasted for 12 weeks, performed one weekly session in a group under the supervision of a researcher in the park's physical environment and three sessions per week individually. Aerobic walking was performed in walking style with moderate to moderate intensity (based on patient tolerance). Resistive exercise movements were performed for muscle strength with moderate to moderate intensity (based on patient tolerance) for each large muscle group twice a week, once grouped. Stretching exercises for pulling the main muscles and tendons were also performed twice a week in a single session, individually and one session. In addition, patients with urinary incontinence were trained and recommended for pelvic floor exercise. Which performs these movements daily.

Category

N/A

2

Description

Control group: No specific action was taken in patients in the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان آموزشی امام خمینی شهرتهران وابسته به دانشگاه علوم پزشکی تهران

Full name of responsible person

عباس مردانی

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Imam Khomeini Hospital، East Nusrat Street, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research of Tehran University of Medical Sciences

Full name of responsible person

Shadan Pedram Razi

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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

Deputy of Research of Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Abbas mardani

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
To protect the privacy of the participants in the study

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available