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Extended intervention on functions in prostate cancer patients

Submission date
04/03/2025

Recruitment status
No longer recruiting

Registration date
11/03/2025

Overall study status
Completed

Last Edited
05/03/2025

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
As one of the common malignant tumors in males, prostate cancer emerges as a serious threat to the life and health and quality of life of patients. I125 seed implantation performs precise local irradiation of prostate cancer tissues by continuously releasing low doses of radiation, which can effectively control the growth and spread of prostate cancer tissues. However, patients experience increased perceived stress, voiding dysfunction, and inadequate self-management after receiving treatment. This study will investigate the effect of extended intervention in the medical community model on perceived stress, voiding function, and self-management ability in patients with prostate cancer underwent I125 seed implantation.

Who can participate?
Patients with prostate cancer treated with I125 seed implantation who were treated at our hospital participated in this trial.

What does the study involve?
This study involves the clinical nursing effect of extended intervention under medical community model on patients with prostate cancer treated with I125 seed implantation.

What are the possible benefits and risks of participating?
The potential benefit of participating in this trial is that patients with prostate cancer treated with I125 seed implantation may recover their physical health faster, The risk is that without sufficient long-term follow-up, prostate cancer may recur and serious complications may occur.

Where is the study run from?
The Second Affiliated Hospital of Wenzhou Medical University (Children's Hospital Affiliated to Wenzhou Medical University) (China)

When is the study starting and how long is it expected to run for?
February 2021 to October 2024

Who is funding the study?
Wenzhou basic scientific research project (Grant No. Y20240442(China)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effect of extended intervention on perceived stress, voiding function and self-management ability in prostate cancer patients treated with I125 seed implantation under medical community model: A randomized clinical trial

Acronym
EI UMCM

Study objectives

Extended interventions under the medical community model are more effective than conventional interventions in reducing perceived stress, improving urinary function, and enhancing self-care abilities in prostate cancer patients

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/02/2024, Ethics Committee of The Second Affiliated Hospital of Wenzhou Medical University (Children's Hospital Affiliated to Wenzhou Medical University) (No. 109 Xueyuan West Road, Lucheng District, Wenzhou City, Zhejiang Province, China, Wenzhou, 325000, China; +86 577-85676879; feykjkcy@126.com), ref: 2024134

Study design
Single center interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Efficacy

Participant information sheet

Health condition(s) or problem(s) studied
Extended intervention under medical community model in prostate cancer patients

Interventions
Brief methodology: the study group received conventional care intervention + extended intervention under medical community model, the control group received conventional care intervention.

Treatment:Before intervention, there was no significant difference in tension and loss of control scores between the two groups ; after intervention, the tension and loss of control scores were significantly lower in the study group.
Before intervention, there was no significant difference in residual urine volume, maximum urinary flow rate, detrusor pressure at maximum urinary flow rate and bladder compliance between the two groups ; after intervention, the study group had significantly lower residual urine volume, higher maximum urinary flow rate, detrusor pressure at maximum urinary flow rate, as well as bladder compliance.
Before the intervention, there was no significant difference in the scores of self-concept, health knowledge level, self-responsibility, and self-care skills between the two groups ; after the

intervention, the scores of self-concept, health knowledge level, self-responsibility, and self-care skills were significantly higher in the study group.
After the intervention, the overall satisfaction rate was notablely higher in the study group.

Total duration of treatment :one month.

Follow-up: Follow up will be conducted one month and three months after intervention. After 3 months, all patients in the study group had their perceived stress and urinary function restored to normal. The self-care ability has also reached a high level. In the control group, 5 patients still had high levels of perceived stress, 3 patients had urinary dysfunction, and 6 patients had weak self-care abilities. Under the guidance and advice of doctors, after 3 weeks of continuous home care, their stress has decreased, their urinary function has gradually returned to normal, and their self-care ability has also been improved.

Randomisation process: In this study, all enrolled patients who met the inclusion criteria were first numbered according to the order of presentation, and then the patients corresponding to the numbers were randomly assigned to the two groups using a random number table generated by computer. Patients with odd numbers entered the study group and even numbered patients entered the control group.

Intervention Type
Behavioural

Primary outcome measure
1. The perceived stress is measured using the Chinese Perceived Stress Scale (CPSS) before intervention and after one month of intervention.
2. Compare the changes of residual urine volume, maximum urinary flow rate, detrusor pressure at maximum urinary flow rate and bladder compliance using clinical observation data from patient medical notes before intervention and after one month of intervention.
3. The self-care ability is measured using the Exercise of Self-care Agency (ESCA) scale before intervention and after one month of intervention.

Secondary outcome measures
Patient satisfaction measured using a self-made satisfaction questionnaire for care interventions after one month of intervention.

Overall study start date
01/02/2021

Completion date
01/10/2024

Eligibility

Key inclusion criteria
1. According to the criteria of "Chinese Guidelines for the Diagnosis and Treatment of Urological Diseases", the diagnosis of prostate cancer was confirmed by MRI, prostate biopsy and other examinations
2. No bone metastasis was found by bone scan
3. The expected survival time of the patients was ≥2 years
4. The patients agreed to participate in this study and signed the informed consent form

Participant type(s)
Patient

Age group
Adult

Lower age limit
56 Years

Upper age limit
70 Years

Sex
Male

Target number of participants
116

Key exclusion criteria
1. Suffering from mental disorders
2. Combined with coagulation dysfunction
3. Heart, brain, kidney and other organ dysfunction
4. Combined with severe liver, kidney, blood system and other primary diseases and malignant tumors

Date of first enrolment
01/02/2022

Date of final enrolment
01/02/2024

Locations

Countries of recruitment
China

Study participating centre
The Second Affiliated Hospital of Wenzhou Medical University (Children's Hospital Affiliated to Wenzhou Medical University)
No. 109 Xueyuan West Road, Lucheng District
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Sponsor information

Organisation
The Second Affiliated Hospital of Wenzhou Medical University

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Sponsor type
Hospital/treatment centre

Website
http://www.wzhealth.com/

Funder(s)

Funder type
Government

Funder Name
Wenzhou basic scientific research project

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from (Aijing Pan,ajpan0876@163.com)

IPD sharing plan summary
Available on request