Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the Impact of Mobile-Based Education on Quality of Life, Anxiety, and Self-Care in Patients Undergoing Open Prostatectomy: A Randomized Controlled Trial Study

Protocol summary

Study aim

Determination the effect of mobile-based education on quality of life, anxiety and self-care in patients undergoing open prostatectomy between intervention and control groups

Design

A phase 3 clinical trial with a control group, featuring parallel groups, non-blinded, and randomized, was conducted on 60 patients.

Settings and conduct

Study place: Operating ward of Shaid Beheshti Hospital in Hamdan; Study population: patients with Benign prostatic hyperplasia; Type of blinding: In this study blinding was not performed

Participants/Inclusion and exclusion criteria

Inclusion criteria: candidates for open prostatectomy via the transvesical approach must be demonstrate a willingness to participate in the study, possess the ability to flow educational content and communicate with the researcher, own an android device and be proficient in its use, and have literacy skills or be accompanied by a literate individual to assist in data completion. Exclusion criteria: individuals currently participating in another clinical trial concurrently, loss of participants during the study due to death, withdrawal of consent during the study, or lack of cooperation from patients in following educational guidance will be excluded.

Intervention groups

The intervention group will receive care education through a communication application provided by the researcher. In the intervention group, assessments related to the quality of life and self-care will be conducted during visits to the physicians office. Subsequently, on the of surgery, anxiety levels will be evaluated, and after the surgery, urinary symptoms, quality of life, and self-care will be assessed at one and three-month intervals. The control group will undergo the evaluations in a similar manner, with the distinction that they receive standard educational materials instead.

Main outcome variables

Quality of life; anxiety; self-care; urinary symptoms.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201127049507N2**
Registration date: **2025-03-29, 1404/01/09**
Registration timing: **prospective**

Last update: **2025-03-29, 1404/01/09**
Update count: **0**

Registration date

2025-03-29, 1404/01/09

Registrant information

Name

Iman Khahan-Yazdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3661 7321

Email address

antenen@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-03-30, 1404/01/10

Expected recruitment end date

2025-09-21, 1404/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Impact of Mobile-Based Education on Quality of Life, Anxiety, and Self-Care in Patients Undergoing Open Prostatectomy: A Randomized Controlled Trial Study

Public title

The Impact of Mobile Education on Quality of Life, Anxiety, and Self-Care in Patients Undergoing Prostate Surgery

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for open prostate surgery via transvesical approach Willingness to participate in the study Ability to follow up on training and communicate with researcher Possessing and android phone and the ability to operate it

Exclusion criteria:

Loss of samples during the study due to mortality Severe mental health disorders Surgery performed in the past six months

Age

To **90 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

A randomized controlled clinical trial, phase 3 on 60 patients, a random sequence is created by an epidemiologist by running an online program on the website (https://www.sealedenvelope.com), due to the use of codes The specialization created by the website also guarantees the allocation hiding.

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

Research Ethics Committees of Hamadan University of Medical Scieneces

Street address

Hamedan, Shahid Fahmideh Blvd., Research Square, Central Headquarters of University of Medical Sciences, 5th Floor

City

Hamadan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Approval date

2025-03-01, 1403/12/11

Ethics committee reference number

IR.UMSHA.REC.1403.874

Health conditions studied

1

Description of health condition studied

Benign neoplasm of prostate

ICD-10 code

D29.1

ICD-10 code description

Benign neoplasm of prostate

Primary outcomes

1

Description

Quality of life in the short form of the World Health Organization quality of life questionnaire

Timepoint

Measurement of quality of life at the start of the study (prior to intervention) and at 1 and 3 months post initiation of educational interventions

Method of measurement

Short form of the World Health Organization quality of life questionnaire

2

Description

State-trait anxiety inventory score

Timepoint

Measurement of preoperative anxiety

Method of measurement

State-trait anxiety inventory

3

Description

Self-care assessment score on the Self-Care Agency

Scale-Revised

Timepoint

Measurement of Self-care at the start of the study (prior to intervention) and at 1 and 3 months post initiation of educational interventions

Method of measurement

Self-care agency scale-revised

4

Description

Score of the Urinary symptom checklist

Timepoint

1 and 3 months post initiation of educational interventions

Method of measurement

Urinary symptom checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients diagnosed with benign prostatic hyperplasia who are candidates for open prostatectomy will receive standard hospital care, in addition to educational interventions related to self care behaviors following surgery, one week prior to the surgical procedure.

Category

Rehabilitation

2

Description

Control group: patients diagnosed with benign prostatic hyperplasia who are candidates for open prostatectomy will receive only standard hospital care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital, Hamadan

Full name of responsible person

Dr. Siamak Daneshvar

Street address

Hamedan - Beginning of Eram Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Behrouz Khanarkaei

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Iman Khahan-Yazdi

Position

Master's degree student

Latest degree

Bachelor

Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

Contact
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Person responsible for updating data

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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