

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### The effect of designed self care educational program on anxiety, stress, depression and complications after TURP surgery in patients with Benign Prostatic Hyperplasia

#### Protocol summary

##### Summary

the aim of this study was to investigate the effects of designed self care educational program on anxiety, stress, depression and complications after TURP surgery in patients with benign prostatic hyperplasia. This study is a quasi-experimental research with two groups: case (n=33) and control (n=34). The samples were BPH patients referred to Milad Hospital in Tehran, who were assigned to the study without any random pre-selection processes. were assigned to the study without any random pre-selection processes. For the case group, self care educational program designed and presented in two sessions, before and after the surgery and was followed over a month after surgery But for patients in the control group did not receive any intervention ; then rate of anxiety, stress and depression in three time include: before surgery, discharge and one month after surgery, by using a standard questionnaire DASS-21 and rate of complications by using Self-Reporting complication checklists was measured and between the two groups were compared.

#### General information

##### Acronym

TURP(Trans urethral resection of the prostate),  
BPH(Benign Prostatic Hyperplasia)

##### IRCT registration information

IRCT registration number: **IRCT2012070610196N1**  
Registration date: **2012-12-10, 1391/09/20**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-12-10, 1391/09/20

#### Registrant information

##### Name

Mehdi Beyramijam

##### Name of organization / entity

Tarbiat Modares University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8288 3813

##### Email address

m.beyramijam@modares.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Tarbiat Modares University

#### Expected recruitment start date

2011-04-04, 1390/01/15

#### Expected recruitment end date

2011-08-21, 1390/05/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of designed self care educational program on anxiety, stress, depression and complications after TURP surgery in patients with Benign Prostatic Hyperplasia

#### Public title

The effect of designed self care educational program on anxiety, stress, depression and complications after TURP surgery in patients with Benign Prostatic Hyperplasia

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

Inclusion criteria of samples: being age from 45 to 80; having literacy of reading and writing; consent to participate in the study; no neurogenic problems such as: Cerebellar ataxia, Cerebrovascular accident, dementia, multiple sclerosis, Parkinson's and other Neurogenic diseases; having the ability to perform self-care activities related to their disease have. Exclusion criteria: occurrence of critical incidents in the life or in the treatment process duration of the intervention that may affect the dependent variable; relinquishment from the study; positive test results for prostate cancer pathology during the intervention period.

#### **Age**

From **45 years** old to **80 years** old

#### **Gender**

Male

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **70**

#### **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**

Tarbiat Modares University

##### **Street address**

Tehran-Jalal Ale Ahmad Highway - Bridge of Nasr-tarbiat modares university

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2010-12-07, 1389/09/16

#### **Ethics committee reference number**

52/74865

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Malignant neoplasm of prostate

#### **ICD-10 code**

C61

#### **ICD-10 code description**

Malignant neoplasm of prostate

## **Primary outcomes**

### **1**

#### **Description**

Anxiety

#### **Timepoint**

Baseline - before discharge - a month after discharge

#### **Method of measurement**

DASS21 Questionnaire

### **2**

#### **Description**

Stress

#### **Timepoint**

Baseline - before discharge - a month after discharge

#### **Method of measurement**

DASS 21 scale

### **3**

#### **Description**

Depression

#### **Timepoint**

Baseline - before discharge - a month after discharge

#### **Method of measurement**

DASS21 Questionnaire

### **4**

#### **Description**

Complications after surgery

#### **Timepoint**

During the first month after discharge

#### **Method of measurement**

Self-report checklist

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention for the experimental group consisted of two sessions on patient self-care issues: the first session (one hour before surgery) includes: understanding the nature of the illness, familiarity with the issues before the operation, the nature of the surgery, results before and after surgery and routines of before and postoperative care and familiarity with diet, exercise, oral health and fluid intake after surgery; then the second session (one hour after surgery) includes: discharge planning and Home-care instructions in areas such as: nutrition and

diet at home, genital hygiene and prevent urinary-genital tract infections, exercise and activity, working, fluid intake to prevent constipation, drug use and sexuality, sitting in the bath daily, during acute urinary irritation and obstruction, which was done face to face and in patient's bedside and using appropriate teaching aids (educational pamphlets, animation files using laptop) and care processes within a month after surgery were followed up by phone by the researcher.

**Category**

Other

**2****Description**

Control: routine care

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Milad Hospital

**Full name of responsible person****Street address**

Tehran, Hakim Highway, Next to Milad Tower, Milad Hospital

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

Mr. Moussavian

**Street address**

Tehran - Jalal Ale Ahmad - Paul Nasr - University - Faculty of Medical Sciences

**City**

Tehran

**Grant name**

پشتیبانی از پایان نامه ها و رساله ها

**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tarbiat Modares University

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

empty

**Person responsible for general inquiries****Contact****Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

Mehdi Bayrami Jam

**Position**

MS in Nursing Education

**Other areas of specialty/work****Street address**

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**City**

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Tarbiat Modares University

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Dr. Monireh Anousheh

**Position**

Associate Academic Member, School of Medical Sciences, Department of Nursing

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*