

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Evaluation of Effectiveness of Biofeedback Therapy on Women with Fecal Outlet Obstruction Disorders

#### Protocol summary

##### Summary

The purpose of Biofeedback is that the patient improve or control his or her reaction voluntarily, with the feedback from Physiological processes that is reachable with electrical sensors. This research is a semi experimental study that is done on 30 women in 15-65 years old with fecal outlet obstruction disorders who have visited surgeon's clinic in Shahrood. Biofeedback is performed once a week during 8 weeks. according to inclusion and exclusion criteria, the questionnaire is completed for each patients, before Biofeedback is performed. after 8 weeks patients are visited and the questionnaires are completed again. Eventually the condition of patients will compared before and after biofeedback therapy and data analysis is done to reach results.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017022132712N1**

Registration date: **2017-05-15, 1396/02/25**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-05-15, 1396/02/25

##### Registrant information

###### Name

Maryam Heydari

###### Name of organization / entity

Islamic Azad University, Shahrood Branch

###### Country

Iran (Islamic Republic of)

###### Phone

+98 23 3236 0080

###### Email address

maryam.h2017@iau-shahrood.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Islamic Azad University, Shahrood Branch

###### Expected recruitment start date

2017-02-19, 1395/12/01

###### Expected recruitment end date

2017-08-23, 1396/06/01

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Evaluation of Effectiveness of Biofeedback Therapy on Women with Fecal Outlet Obstruction Disorders

###### Public title

Effectiveness of Biofeedback Therapy on Fecal Outlet Obstruction Disorders.

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion criteria: Having fecal outlet obstruction disorder; Having history of defecation with excessive straining and normal times of defecation; Constipation is not caused by secondary factors; Muscle weakness is caused by curable reasons like rectocele and rectal prolapse; Lacking of colon's pathology that is creating constipation like Colorectal cancer. Exclusion criteria: Having Serious illnesses that effects on quality of life like sever diabetes, Immunological disorders, psychological disorders and addiction; Patients who have past convalescence over 3 months; The patients under 15 or over 65; Having other disorders like fecal incontinence;

Use of any other treatment methods during research.

### Age

From **15 years** old to **65 years** old

### Gender

Female

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **30**

### Randomization (investigator's opinion)

N/A

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Single

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Islamic Azad University, Shahrood

##### Street address

Islamic Azad University of Shahrood Branch building,  
Daneshgah Blvd, Shahrood, Semnan Province

##### City

Shahrood

##### Postal code

#### Approval date

2017-01-21, 1395/11/02

#### Ethics committee reference number

IR.IAU.SHAHROOD.REC.1395.14

## Health conditions studied

### 1

#### Description of health condition studied

Fecal outlet obstruction disorders

#### ICD-10 code

K59

#### ICD-10 code description

Other functional intestinal disorders

## Primary outcomes

### 1

#### Description

Evaluate the severity of clinical symptoms before and after biofeedback therapy

#### Timepoint

Early of intervention and 8 weeks after that

#### Method of measurement

Questionnaire

## Secondary outcomes

### 1

#### Description

Evaluate the duration of defecation before and after biofeedback therapy

#### Timepoint

Early intervention and 8 weeks after that

#### Method of measurement

Questionnaire

### 2

#### Description

Evaluate the times of defecation before and after biofeedback therapy

#### Timepoint

Early intervention and 8 weeks after that

#### Method of measurement

Questionnaire

## Intervention groups

### 1

#### Description

Biofeedback therapy, Training pelvic muscle exercise and Recommendations for having a correct life style

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rasoul Akram Medical Complex

##### Full name of responsible person

Maryam Heydari

##### Street address

##### City

Shahrood

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University, Shahrood Branch

##### Full name of responsible person

Dr.Saheb Ali Manafii

**Street address**

Islamic Azad University of Shahrood Branch building,  
Daneshgah Blvd, Shahrood, Semnan Province

**City**

Shahrood

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

Yes

**Title of funding source**

Islamic Azad University, Shahrood Branch

**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**

Islamic Azad University, Shahrood Barnch

**Full name of responsible person**

Maryam Heydari

**Position**

Student

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

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

Dr.Fateme Amirkhalili

**Position**

General Surgeon Specialist

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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**Position**

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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*