Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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

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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

Evaiuate 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

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

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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