

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The comparison between the effects of biofeedback with pelvic floor muscle training and biofeedback alone on chronic constipation in adult females: a randomized controlled trial

Protocol summary

Study aim

The comparison between the effects of biofeedback with pelvic floor muscle training on chronic constipation in adult females

Design

A randomized controlled clinical trial, single blinded. The sample size is 66 (33 participants in each group).

Settings and conduct

This study will be conducted at specialized clinic of Tabriz University of Medical Sciences. Thirty three women in the age range of 18 to 54 years will participate in the study. Symptoms of chronic constipation will be assessed and confirmed by a gastroenterologist. This study will be double-blinded. Data assessor and statistician will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Chronic constipation for 6 months, No medication during last two weeks, Age between 18-54 years. Exclusion criteria: systemic diseases, Irritable bowel syndrome, Secondary constipation to various factors, Pregnant and lactating women, Psychological disorders, Addiction and Alcohol abuse, Understanding problems

Intervention groups

Intervention group 1 (Biofeedback group): Individuals in this group will receive biofeedback with Enraf 632x Myome Biofeedback device, two 30- minute sessions per week, for 3 months. Intervention group 2 (Biofeedback with Pelvic Floor Muscle Exercises group): In this group as in the previous group, biofeedback intervention will be performed and the supervised graded pelvic floor muscles exercises will be done for each patient.

Main outcome variables

Constipation severity, intensity of sphincter and abdominal muscle activity, resting and maximal anal pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140811018760N6**

Registration date: **2020-03-06, 1398/12/16**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-06, 1398/12/16**

Update count: **0**

Registration date

2020-03-06, 1398/12/16

Registrant information

Name

Fariba Ghaderi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1333 4647

Email address

ghaderif@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-19, 1398/11/30

Expected recruitment end date

2020-07-20, 1399/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison between the effects of biofeedback with pelvic floor muscle training and biofeedback alone on chronic constipation in adult females: a randomized controlled trial

Public title

Effect of biofeedback in chronic constipation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Symptoms of chronic constipation for 6 month No drug use in intervention groups during last two weeks Age range of 18-54 years

Exclusion criteria:

Presence of systemic diseases Irritable bowel syndrome Secondary constipation anatomical, endocrine, metabolic, neurological, surgical factors Blood diseases or taking anticoagulants drug such as Heparin and Warfarin Abdominal aneurysm Pregnant and lactating women Presence Pacemaker Psychological and psychiatric disorders Addiction and Alcohol abuse Understanding problems

Age

From **18 years** old to **54 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Investigator

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Adult women with chronic constipation, if appropriate, were randomly assigned in the two intervention and control groups using blocks of size 6 and 9 blocks with 1:1 allocation ratio. For the allocation concealment, the type of intervention received is written on a piece of paper and placed inside the opaque envelopes and the back of the envelope will be numbered. The envelopes will be opened according to the entry of the participants and the type of group for each patient will be specified accordingly.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study will be single blinded. Because of exercise nature in one group, participants in this study cannot be blind in which group they are. So only the investigator (data assessor) will be blind. The statistician will also be blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Rehabilitation faculty, Daneshgah avenue, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5167631444

Approval date

2019-12-08, 1398/09/17

Ethics committee reference number

IR.TBZMED.REC.1398.937

Health conditions studied

1

Description of health condition studied

Chronic constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes

1

Description

Constipation severity

Timepoint

Before intervention and at the end of the intervention

Method of measurement

Comprehensive constipation questionnaire

Secondary outcomes

1

Description

Evaluation of the intensity of anal sphincter muscle activity

Timepoint

Before intervention and at the end of the intervention

Method of measurement

The intensity of sphincter muscle activity will be measured using an electromyograph (EMG)

2

Description

Evaluation intensity of abdominal muscle activity

Timepoint

Before intervention and at the end of the intervention

Method of measurement

The intensity of abdominal muscles activity will be measured using an electromyograph (EMG)

3

Description

Evaluation anal resting pressure

Timepoint

Before intervention and at the end of the intervention

Method of measurement

The anal resting pressure will be measured using the anorectal manometry

4

Description

Evaluation anal squeeze pressure

Timepoint

Before intervention and at the end of the intervention

Method of measurement

The anal squeeze pressure will be measured using the anorectal manometry

Intervention groups

1

Description

Intervention group 1: Individuals in this group will receive Visual Therapy with Enraf (632x Myomed) biofeedback device, two 30- minute sessions per week, for 3 months. Step 1, Patient education and awareness;The paradoxical state of sphincter voluntary contraction or inability to relax the anal muscles during excretion is explained to the patient. Pushing during excretion (like stool excretion): At this stage, superficial electrodes are placed on the abdominal muscles to determine how they are operated during excretion. Stage III; Pelvic floor relaxation technique: At this stage the patient is flanked and the rectal probe is placed by the therapist then the patient will be taught how to facilitate the rectal canal and the rectum using a biofeedback monitor. Last step; the patient is asked to relax the anal canal while exerting pressure on the abdomen (abdominal rectus muscle and diaphragm). In the first stage, the breathing technique must be corrected when attempting to defecate. Bearing down maneuvers are taught to the patient.

Category

Treatment - Other

2

Description

Intervention group 2: In this group, the biofeedback intervention will be performed as in the previous group and the graded supervised pelvic floor muscle exercises

will be conducted by physiotherapist for each patient. The patient will perform one session per week of exercise under the supervision of a physiotherapist and will be given progressive exercise weekly.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Fariba Ghaderi

Street address

Faculty of rehabilitation, Golgasht Ave, Tabriz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jooyban

Street address

Vice-Chancellor for Research and Technology,
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Fariba Ghaderi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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

Tabriz University of Medical Sciences

Full name of responsible person

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Position

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Study protocol, statistical analysis plan, and informed consent form will be available to share with other investigators if they request by email.

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

Only available for people working in academic institutions in Iran

Under which criteria data/document could be used

In case of journal or reviewers request for data set

From where data/document is obtainable

Via email and giving documents to prove their identity for administrator Dr Fariba Ghaderi
ghaderimailbox@gmail.com OR ghaderif@gmail.com

What processes are involved for a request to access data/document

Sending email and documents to prove their identity

Comments