Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 manometery

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 manometery

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
City
Tabriz
Province
East Azarbaijan
Postal code
5167631444
Phone
+98 41 3337 5359
Email
ghaderif@tbzmed.ac.ir

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, Daneshgah avenue, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5167631444
Phone
+98 41 3334 5121
Fax
+98 41 3334 5121
Email
ghaderif@tbzmed.ac.ir
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
Street address
Rehabilitation Faculty, Daneshgah avenue, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5167631444
Phone
+98 41 3334 5121
Fax
+98 41 3334 5121
Email
ghaderif@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Fariba Ghaderi
Position
Associate professor
Latest degree
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Other areas of specialty/work
Physiotherapy
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Province
East Azarbaijan
Postal code
5167631444
Phone
+98 41 3334 5121
Fax
+98 41 3334 5121
Email
ghaderif@tbzmed.ac.ir

Person responsible for updating data

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
Street address
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5167631444
Phone
+98 41 3334 5121
Fax
+98 41 3334 5121
Email
ghaderif@tbzmed.ac.ir

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