

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The Effect of Biofeedback Therapy (BFT) with Cognitive Behavioral Therapy (CBT) on the Quality of Life, Anxiety, Depression and Somatic Symptoms in Patients with Dyssynergic Defecation.

Protocol summary

Study aim

The effect of of biofeedback therapy and cognitive behavioral therapy on quality of life, psychological and physical symptoms in dyssynergic defecation patients.

Design

A total of 45 patients enrolled between April 2017 and December 2017, were randomly allocated to 3 parallel groups in a controlled clinical trial.

Settings and conduct

The patients were divided in three groups.They received biofeedback therapy with cognitive-behavior therapy, biofeedback therapy, and standard therapy. Assessment were done by questionnaires such as; the Short Form-36 quality of life , Spielberger Anxiety, Beck depression and Constipation scoring system, also digital rectal exam before and after treatment.This study conducted in Physiotherapy clinic of Rehabilitation Faculty in Iran University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion; Patients with defecation disorder, hard stools, incomplete evacuation and digital manipulation in more than 1/4 of bowel movements.Diagnosis of paradoxical function of puborectalis with examination. Exclusion; history of anorectal surgery and tumors, structural anorectal disorders leads to surgery,constipation because of endocrine and metabolic diseases, severe cardiovascular, respiratory, neurological, psychological problems.

Intervention groups

Intervention group ; biofeedback therapy (BFT: correction of defecation pattern by pelvic floor relaxation training using biofeedback device (Enraf.co) during 60 minutes twice a week for 12 sessions; then once a week for 6 sessions) and cognitive behavioral therapy (CBT: identification of self-defeating behavior patterns and thoughts in six sessions.). control 1; BFT (as above) control 2; standard therapy (STT: advise about nutrition

and daily exercises and control for three months.)

Main outcome variables

Quality of life, physical symptom: constipation, psychological symptoms: anxiety, depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141115019957N2**

Registration date: **2019-09-10, 1398/06/19**

Registration timing: **retrospective**

Last update: **2019-09-10, 1398/06/19**

Update count: **0**

Registration date

2019-09-10, 1398/06/19

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 7124

Email address

nikjooy.a@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-04-19, 1393/01/30

Expected recruitment end date

2019-03-16, 1397/12/25

Actual recruitment start date

2014-04-19, 1393/01/30

Actual recruitment end date

2019-03-16, 1397/12/25

Trial completion date

2019-03-16, 1397/12/25

Scientific title

The Effect of Biofeedback Therapy (BFT) with Cognitive Behavioral Therapy (CBT) on the Quality of Life, Anxiety, Depression and Somatic Symptoms in Patients with Dyssynergic Defecation.

Public title

The effect of cognitive behavioral therapy and biofeedback on physical-psychological symptoms of patients with dyssynergic defecation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The patients with functional chronic constipation and strain for defecation The patients who had hard stools, incomplete evacuation and digital manipulation in more than 1/4 of bowel movements The patients with diagnosis of paradoxical contraction of the puborectalis muscle during straining established by digital rectal examination (DRE) and also diagnostic test such as anorectal manometry or defecography or balloon expulsion test

Exclusion criteria:

History of anorectal surgery Anorectal tumors Structural anorectal disorders led to surgery Constipation because of endocrine diseases Severe cardiovascular problems Severe respiratory problems Severe neurologic problems Severe psychological problems Constipation because of metabolic diseases

Age

From **25 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Actual sample size reached: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was performed using Excel software that way, we generated random numbers from 1 to 3, and numbers between 0 and 1 was assigned into the first group, numbers between 1 and 2 (except for 1) was assigned into the second group and the numbers between 2 and 3 (except 2) was assigned into the third group of treatment.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Factorial

Other design features

Biofeedback with CBT treatment has not been done for the problem of dyssynergic defecation until now

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2015-10-17, 1394/07/25

Ethics committee reference number

IR.IUMS.REC.1394.19397

Health conditions studied**1****Description of health condition studied**

Patients with dysfunctional defecation (dyssynergic defecation)

ICD-10 code

K59.09

ICD-10 code description

Other constipation

Primary outcomes**1****Description**

Anxiety

Timepoint

before and after intervention

Method of measurement

Spielberger Inventory

2**Description**

Depression

Timepoint

before and after intervention

Method of measurement

Beck Inventory

3

Description

Constipation

Timepoint

Before and after intervention

Method of measurement

The symptoms of constipation were checked by the Constipation Scoring System (CSS) before and after the treatment, with a 30-point questionnaire, which points to more severity of constipation.

4

Description

Quality of life

Timepoint

Before and after intervention

Method of measurement

Quality of life questionnaire SF36

5

Description

Paradoxical contraction of Puborectalis muscle

Timepoint

Before and after treatment

Method of measurement

Digital rectal examination

Secondary outcomes

empty

Intervention groups

1

Description

The treatment of the "Intervention group" included biofeedback therapy simultaneously with cognitive behavioral therapy. A physiotherapist specialized in pelvic floor dysfunction conducted the Biofeedback therapy. At the beginning of the first treatment session; the physiology of defecation and pathophysiology of dyssynergic defecation were explained to the patients. The biofeedback was done by simulated defecation which synchronized with visual /verbal feedback method for training the pelvic floor relaxation. This procedure was consisting of inserting a pressure probe into the patient's rectum, and also a surface electrode on abdominal muscles, to monitor the activity of the muscles. Then, they were taught "Abdominal Recto Anal Coordination Training" method, to coordinate their abdominal push effort and concurrent relaxation of the anal sphincter and the puborectalis muscles which depicted by decreased anal pressure on the monitor. The duration of the biofeedback therapy session was 60 minutes twice a week for 12 sessions; then once a week for 6 sessions, that is, 18 sessions in total. Cognitive behavioral therapy was conducted by a psychologist consisting of six sessions, through which the patients were helped to identify the self-defeating

behavior patterns and maladaptive thoughts that could have a harmful effect on mental well-being, life functioning and symptomatic experience. The treatment sessions were held individually, once a week, for 45 minutes, including: 1- History taking and rapport establishing. 2- Clarifying the effectiveness of psychological treatment on reducing physical symptoms. 3- Identifying psychological disorders, training the treatment model and drawing the relationship between thoughts, feelings and behaviours on mental disorder with considering the patient's problem. 4- Teaching a suitable technique for evaluating thoughts (credibility and usefulness). 5- Training for identifying the cognitive errors and providing coping skills and problem solving. 6- Concluding the treatment pathway and providing a solution to prevent recurrence.

Category

Treatment - Other

2

Description

The treatment of the "Control group 1" only included Biofeedback therapy. A physiotherapist specialized in pelvic floor dysfunction conducted the Biofeedback therapy. At the beginning of the first treatment session; the physiology of defecation and pathophysiology of dyssynergic defecation were explained to the patients. The biofeedback was done by simulated defecation which synchronized with visual /verbal feedback method for training the pelvic floor relaxation. This procedure was consisting of inserting a pressure probe into the patient's rectum, and also a surface electrode on abdominal muscles, to monitor the activity of the muscles. Then, they were taught "Abdominal Recto Anal Coordination Training" method, to coordinate their abdominal push effort and concurrent relaxation of the anal sphincter and the puborectalis muscles which depicted by decreased anal pressure on the monitor. The duration of the Biofeedback therapy session was 60 minutes twice a week for 12 sessions; then once a week for 6 sessions, that is, 18 sessions in total.

Category

Treatment - Other

3

Description

The "Control group 2" received standard treatment. This group was avoided from medical treatment, and was encouraged to take sufficient fiber, water and taking part in daily exercises. Also, the patients of this group were trained attempting to have a bowel movement twice a day, usually 30 minutes after meals or walking (Timed Toilet Training). During attempted defecation, the straining should not be taken more than 5 minutes. The patients were advised not to use digital maneuvers to disimpact the fecal. Also they were taught the correct position of defecation and diaphragmatic breathing during defecation for increasing intra-abdominal pressure for facilitating the defecation process. Duration of treatment was three months and the patients were controlled once a week on the phone.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Physiotherapy Clinic, Faculty of Rehabilitation Sciences, Iran University of Medical Sciences, Tehra

Full name of responsible person

Afsaneh Nikjooy

Street address

Iran University of Medical Sciences, Faculty of Rehabilitation Sciences, Shah Nazari St, Mother Square, Mirdamad Alley, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 21 2222 7124

Email

nikjooy.a@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Kazem Malakouti

Street address

Deputy of Research of Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Phone

+98 21 86701

Email

malakouti.k@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Afsaneh Nikjooy

Position

Assistant Professor in Iran University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 86701

Email

nikjooy.a@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Afsaneh Nikjooy

Position

Assistant Professor at Iran university of medical sciences

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 86701

Email

nikjooy.a@iums.ac.ir

+98 21 86709

Email

nikjooy.a@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Afsaneh Nikjooy

Position

Assistant Professor at Iran university of medical sciences

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway,

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available