Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of biofeedback therapy and posterior tibial nerve stimulation alone versus combined treatment on improving pelvic floor muscle activity, sign and quality of life in femals with chronic dyssynergic constipation and stress urinary incontinence: asingle blind randomized controlled trial

Protocol summary

Study aim

The aim of this study is to provide an effective treatment method to reduce symptoms, reduce treatment duration, increase quality of life and thus reduce treatment costs in patients with simultaneous disorder of chronic dyssynergic constipation and stress urinary incontinence.

Design

In this clinical trial study, 87 people will be selected according to the entry criteria and data will be collected. we will conduct subsequent sampling through sorting through background variables. We divide people into three groups based on the randomization table.

Settings and conduct

Biofeedback:coordination between abdominal muscles and the pelvic floor.From the 7 session, the treatment goes to computer games, the treatment will be 15 sessions and 3 sessions every week for 20 minutes in each session. In the Ectrical stimulation method, it is a bilateral method with a frequency of 10-14 and a diversion of 200-220 , for 15 sessions, 3 sessions of 30 minutes each week. The Combination group will receive both treatments. Ahvaz Rehabilitation Faculty.

Participants/Inclusion and exclusion criteria

Women with the simultaneous disorder of chronic dyssynergic constipation and stress urinary incontinence are included in the study, People with diseases and interfering drugs are excluded.

Intervention groups

Biofeedback group therapy alone Tibial nerve electrical stimulation treatment group alone The other group combined treatment of biofeedback and electrical stimulation of the tibial nerve

Main outcome variables

Determining and comparing the effect of electrical stimulation, biofeedback and combined treatment on the quality of life, the amount of urine output, the level of pelvic floor muscle activity and the duration of treatment in women with simultaneous disorders of chronic dyssynergic constipation and stress urinary incontinence.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230228057560N1**
Registration date: **2023-05-06, 1402/02/16**
Registration timing: **prospective**

Last update: **2023-05-06, 1402/02/16**
Update count: **0**

Registration date

2023-05-06, 1402/02/16

Registrant information

Name

FATEMEH oraki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3391 1287

Email address

fatemehorakii@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-10, 1402/02/20

Expected recruitment end date

2024-03-10, 1402/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of biofeedback therapy and posterior tibial nerve stimulation alone versus combined treatment on improving pelvic floor muscle activity, sign and quality of life in femals with chronic dyssynergic constipation and stress urinary incontinence: asingle blind randomized controlled trial

Public title

Treatment of women with constipation and urinary incontinence

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 18 to 60 Concomitant presence of constipation and stress urinary incontinence At least 12 months have passed since symptoms Have not responded to standard medical treatments for constipation and adherence to diet not receiveing treatment regarding these two disorders. Having at least two Criterion of the Rome IV criteria

Exclusion criteria:

Unsuccessful history of biofeedback therapy Uncontrolled cardiovascular, kidney and liver diseases Back, hip and/or hip joint dysfunction Diabetes Chronic obstructive pulmonary disease Sexual problems Use of medications (diuretics, sympathomimetics/sympatholytic), parasympathomimetic / parasympatholytic) Spinal cord injury Patients with a history of mental illness Drug-induced constipation Metabolic, endocrine, neurological disorders History of pelvic surgery Pregnancy Active intestinal disease and fissure Neurological diseases (such as multiple sclerosis, stroke) Urine test and positive urine culture History of radiation therapy or hormone therapy in the last six months Prolapse of the pelvic organs more than grade 2 (more than 1 cm below Hyman's membrane during the examination in the stretched state of the pelvic floor. Grading will be done through the quantitative system of pelvic organ prolapse and by a gynecologist or pelvic floor physiotherapist. This The method has 5 grades from grade 0 to 4, grade 0 indicates the absence of prolapse, grade 1 is less than 1 cm below Hyman's curtain, grade 2 is more than 1 cm below Hyman's curtain, grade 3 is more than 1 cm. below the hymen, but does not protrude more than 2 cm from the entire length of the vagina, and in grade 4, the lower genital system is completely deviated They were not able to contract the pelvic floor muscles during finger examination Active or recurrent urinary tract infection

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **87**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

In order to select the participants in this study, we will conduct subsequent sampling through sorting through background variables. We divide people into three groups based on the randomization table. One group receives biofeedback treatment alone, one group receives tibial nerve electrical stimulation treatment alone, and the other group receives combined biofeedback and tibial nerve electrical stimulation treatment.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahwaz Jundi shapoor univercity of medical sciences

Street address

No 81, 6 West Ave, Kyan pars Blvd

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Khouzestan

Postal code

6155844474

Approval date

2023-04-08, 1402/01/19

Ethics committee reference number

IR.AJUMS.REC.1402.006

Health conditions studied

1

Description of health condition studied
Constipation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Quality of life
Timepoint
At the beginning of treatment, every five sessions, at the end of treatment and three months after treatment
Method of measurement
Questionnaires

2

Description
Treatment time
Timepoint
At the beginning of treatment, every five sessions, at the end of treatment and three months after treatment
Method of measurement
GEE model

3

Description
Frequency of incontinence
Timepoint
At the beginning of treatment, every five sessions, at the end of treatment and three months after treatment
Method of measurement
Three day bladder diary

4

Description
Activity of pelvicfloor muscles
Timepoint
At the beginning of treatment, every five sessions, at the end of treatment and three months after treatment
Method of measurement
Examining the strength, resting tone, resting activity and sneezing or coughing pelvic floor muscles through electromyography

Secondary outcomes

1

Description
Quality of life
Timepoint
First session, every five sessions, end of treatment and three months after treatment
Method of measurement
Questionnaires

2

Description
Pelvic floor muscle activity
Timepoint
First session, every five sessions, end of treatment and three months after treatment
Method of measurement
Electromyography

3

Description
Treatment time
Timepoint
First session, every five sessions, end of treatment and three months after treatment
Method of measurement
GEE model

4

Description
Frequency of incontinence
Timepoint
First session, every five sessions, end of treatment and three months after treatment
Method of measurement
Three day bladder diary

Intervention groups

1

Description
Intervention group: Biofeedback
Category
Rehabilitation

2

Description
Intervention group: Electrical stimulation
Category
Rehabilitation

3

Description
Intervention group: Combination
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Musculoskeletal Research Center, Jundishapur Rehabilitation Faculty, Ahvaz
Full name of responsible person
Fatemeh Oraki koohshoori

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Vice President of Research and Technologyجم
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz University of Medical Sciences
Proportion provided by this source
1
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
Ahvaz University of Medical Sciences
Full name of responsible person
fatemeh oraki koohshoori
Position
PHD physiotherapy student
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Because pelvic floor disorders are taboo

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