Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effects of adding biofeedback to the pelvic floor muscles strengthening exercises on the treatment of women with urinary incontinence, a single-blinded randomized clinical trial

Protocol summary

Study aim
Studying the effects of pelvic floor muscles strengthening exercises with and without biofeedback on surface EMG variables including maximum and mean pelvic floor muscles strength and on the incontinence severity.

Design
A single-blind randomized clinical trial, with a parallel control group, consisting of 40 patients, done between July 2019 and March 2020, followed for 1 month.

Settings and conduct
The study population included all patients who referred to the gynecology and obstetrics clinic of Shohada Tajrish Hospital with a confirmed diagnosis of urinary incontinence. They were randomly divided into control and treatment groups. Physicians and therapists were blind to the patient groups. There was no ability to blind patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria: women aged 35 to 75 years with an approved diagnosis of urinary incontinence. Exclusion criteria: being single; history of diabetes mellitus, previous pelvic floor surgery, spinal cord injury, or pelvic trauma.

Intervention groups
Intervention group: Pelvic floor strengthening exercises plus biofeedback therapy. Control group: pelvic floor strengthening exercises only.

Main outcome variables
Mean & Maximum pelvic floor muscles strength, ICIQ-SF questionnaire findings

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20201130049543N2**
Registration date: **2021-06-19, 1400/03/29**
Registration timing: **retrospective**

Last update: **2021-06-19, 1400/03/29**
Update count: **0**

Registration date
2021-06-19, 1400/03/29

Registrant information
Name
Fateme Hojjati
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-07-23, 1398/05/01
Expected recruitment end date
2020-03-20, 1399/01/01
Actual recruitment start date
2019-08-06, 1398/05/15
Actual recruitment end date
2020-04-18, 1399/01/30
Trial completion date
2020-08-20, 1399/05/30

Scientific title
The effects of adding biofeedback to the pelvic floor muscles strengthening exercises on the treatment of women with urinary incontinence, a single-blinded

randomized clinical trial

Public title
Biofeedback and urinary incontinence
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women Aged 35-75 years Confirmation of the diagnosis of urinary incontinence (stress, urgency, or mixed type) by a gynecologist
Exclusion criteria:
history of diabetes previous pelvic floor surgery history of spinal cord injury history of pelvic trauma being single
Age
From **35 years** old to **75 years** old
Gender
Female

Phase
N/A
Groups that have been masked

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

Sample size
Target sample size: **40**
Actual sample size reached: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, simple randomization by lottery or sortition method was used. According to the number of patients (40 patients), the numbers were considered from 1 to 40. The numbers were written on the cards. After placing the cards in closed envelopes, each patient randomly selected one of the envelopes. The number of each patient was delivered in a sealed envelope and only the doctor and therapist in charge of laser treatment were aware of its contents. Patients with envelopes containing numbers 1 to 20 were allocated in the control group, numbers 21 to 40 were in the biofeedback group.
Blinding (investigator's opinion)
Single blinded
Blinding description
This was a single-blinded study. A physical medicine and rehabilitation specialist (responsible for initial evaluation and re-evaluation after treatment and also teaching the patient how to do the exercises) was blind to each patient's treatment group. Another physical medicine and rehabilitation specialist was responsible for conducting biofeedback treatment sessions for patients in the second group (exercise + biofeedback). Due to the fact that providing biofeedback in the form of sham (placing the probe in the vagina but with the device turned off) can cause errors in the treatment process (feeling the probe in the vagina itself is a kind of feedback), sham-biofeedback was not done in the control group, so patients blinding could not be done.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iran National Committee for Ethics in Biomedical Research
Street address
13th floor, Block A, Ministry of Health, Treatment and Medical Educatio, Iran TV Street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۹۴۳۴۷۱
Approval date
2015-08-14, 1394/05/23
Ethics committee reference number
IR.SBMU.RAM.REC.1394.268

Health conditions studied

1

Description of health condition studied
Urinari Incontinence
ICD-10 code
R39.81
ICD-10 code description
Functional urinary incontinence

Primary outcomes

1

Description
Urinary incontinence severity
Timepoint
Before and 1 month after treatment
Method of measurement
ICIQ-SF questionnaire

Secondary outcomes

1

Description
Mean strength of pelvic floor muscles
Timepoint
Before and 1 month after treatment
Method of measurement

Surface electromyography

2

Description
Maximum strength of pelvic floor muscles
Timepoint
Before and 1 month after treatment
Method of measurement
Surface electromyography

Intervention groups

1

Description
Intervention group: Performing pelvic floor strengthening exercises along with treatment sessions using a biofeedback device. The duration of treatment was 4 weeks and 7 days a week, they performed pelvic floor strengthening exercises three times a day for 15 minutes. 2 sessions of 20 minutes per week, biofeedback treatment without electrical stimulation was also performed.
Category
Treatment - Devices

2

Description
Control group: Doing pelvic floor strengthening exercises. The duration of treatment was 4 weeks and 7 days a week, they performed pelvic floor strengthening exercises three times a day for 15 minutes.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohadaye Tajrish Hospital
Full name of responsible person
Dr. Fateme Hojjati
Street address
Tajrish Square, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Alireza Zali
Street address
Shahid Arabi St, Yemen St, Shahid Chamran highway, Tehran, Iran.
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Web page address
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Fateme Hojjati
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The study will be published as an article without patient information containing the findings and questionnaires used.
When the data will become available and for how long
Start accessing immediately after printing results
To whom data/document is available
For all health and technology activists
Under which criteria data/document could be used
Information can be used with respect to copyright.
From where data/document is obtainable
Send the request to the email of the corresponding author. Fatemehojjati@yahoo.com
What processes are involved for a request to access data/document
If you send an e-mail request and submit a form to confirm the identity of the applicant, the information will be sent within a week.
Comments