Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of biofeedback and repetitive transcranial magnetic stimulation on pelvic floor muscles function in women with urinary incontinence

Protocol summary

Study aim

Comparing the effect of biofeedback and repeated transcranial magnetic stimulation on pelvic floor muscle function in urinary incontinence women

Design

A randomized clinical trial with a control group and two groups with different therapeutic interventions, and parallel design, double-blind, will be conducted on 33 patients. Block balanced randomization method is used for randomization.

Settings and conduct

The study will be conducted at Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences. Urinary incontinence patients fall into one of three groups by accident. The evaluator and the patients are not aware of the allocation method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women 35 to 70 years old with urinary incontinence; Urine loss of more than 1 gram per hour and confirmed by a one-hour test pad; Associated sexual impotence. Exclusion criteria: History of cesarean section; Pelvic organ prolapse; Active or frequent urinary tract infections; The presence of a copper IUD in the uterus; Pregnancy or childbirth less than 6 months; History of surgery in the abdomen and pelvis; History of constipation;

Intervention groups

RTMS intervention group receives 20 minutes of inhibitory pusles applied on supplementory area of cortex. The other group intervention includes a combination of 15 minutes of electromyographic biofeedback with vaginal probe and progressive exercises of pelvic floor muscles. The control group only receives routine pelvic floor physiotherapy exercises including Kegel exercises. Treatment sessions will be held 3 times a week for a total period of 3 weeks.

Main outcome variables

Average work of the pelvic floor muscles; Average relaxation of pelvic floor muscles; Minimum contraction of pelvic floor muscles; Maximum contraction or peak of pelvic floor muscles; ICIQ-VS questionnaire score; Displacement of the bladder surface

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230305057630N1**
Registration date: **2023-05-09, 1402/02/19**
Registration timing: **prospective**

Last update: **2023-05-09, 1402/02/19**
Update count: **0**

Registration date

2023-05-09, 1402/02/19

Registrant information

Name

Maryam Miri

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-20, 1402/02/30

Expected recruitment end date

2024-05-19, 1403/02/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of biofeedback and repetitive transcranial magnetic stimulation on pelvic floor muscles function in women with urinary incontinence

Public title
Comparing the effects of biofeedback and brain stimulation treatments on pelvic floor muscle function in women with urinary incontinence
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women aged 35 to 70 years with urinary incontinence as the main clinical complaint, without urgent symptoms Urine loss of more than 1 gram per hour should be confirmed by a one-hour test pad The simultaneous presence of sexual disorders and impotence with urinary incontinence Absence of chronic degenerative diseases that affect muscle and nerve tissues Absence of any degree of pelvic organ prolapse (POP) Absence of active or recurrent urinary tract infections (UTIs) Absence of vulvovaginitis Absence of atrophic vaginitis Absence of copper IUD in the uterus Absence of pregnancy or childbirth less than 6 months Not suffering from diabetes, neurological disease, mental illness, and debilitating chronic diseases such as kidney failure and heart pacemakers. Absence of taking drugs that affect urination No history of surgical or drug treatment of SUI No history of abdominal and inguinal hernia No history of any surgery in the abdomen and pelvis (due to adhesions in the area and impact on the bladder) Absence of constipation No history of seizures
Exclusion criteria:
Having a urinary infection History of cesarean section Unwillingness to cooperate Suffering from chronic degenerative diseases that affect muscle and nerve tissues Presence of any degree of pelvic organ prolapse (POP) Presence of active or recurrent urinary tract infections (UTIs) Presence of vulvovaginitis Presence of atrophic vaginitis Presence of a copper IUD in the uterus Pregnancy or childbirth less than 6 months Having diabetes, neurological disease, mental illness and debilitating chronic diseases such as kidney failure and heart pacemaker Presence of drugs that affect urination History of surgical or drug treatment of SUI History of abdominal and inguinal hernia Having a history of any surgery in the abdomen and pelvis (due to adhesions in the area and impact on the bladder) Presence of constipation History of seizures
Age
From **35 years** old to **70 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **33**
Randomization (investigator's opinion)
Randomized
Randomization description
To use the random number table, the researcher first determines the direction of reading the numbers in the table (up, down, left or right). The researcher will consider the numbers 00-24 for the biofeedback group, the numbers 25-49 for the rTMS group, and the numbers 50-74 for the PFMT group. Then the researcher puts her hand on one of the numbers and moves in one of the predetermined directions and records the numbers and assigns them to different groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patient receives the type of intervention or control group in sealed envelopes that are coded. Coding is done by one of the colleagues of the project. The evaluator is blind to the grouping of the participants and the participants are blind to the type of interventions of the opposite group. According to Pan et al.'s study in 2020 for the sham group, the subjects received the same number of stimuli whose parameters are the same as the active group. However, the coil is rotated 90 degrees and only 1 wing will be in contact with the edge on the scalp, producing the same sound. Patients will not be familiar with the difference between rTMS-Sham and active rTMS in acoustic and tactile aspects.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Semnan University Of Medical Sciences and Health Services
Street address
Basij Blvd, Semnan University of Medical Sciences
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Semnan
Postal code
3514799442
Approval date

2023-03-18, 1401/12/27

Ethics committee reference number

IR.SEMUMS.REC.1401.336

Health conditions studied

1

Description of health condition studied

Urinary incontinence

ICD-10 code

N39.3

ICD-10 code description

Stress incontinence (female) (male)

Primary outcomes

1

Description

Evaluation of urinary incontinence and vaginal symptoms

Timepoint

Before and after the intervention and one month after the last treatment session

Method of measurement

International Consultation on Incontinence Questionnaire Vaginal Symptoms Module questionnaire

2

Description

The volume of urine loss

Timepoint

Before and after the intervention and one month after the last treatment session

Method of measurement

One hour pad test

Secondary outcomes

1

Description

Bladder displacement amount

Timepoint

Before and after the intervention and one month after the last treatment session

Method of measurement

Ultrasonography

2

Description

Strength and endurance of pelvic floor muscles

Timepoint

Before and after the intervention and one month after the last treatment session

Method of measurement

Perineometer

3

Description

Strength and endurance of pelvic floor muscles

Timepoint

Before and after the intervention and one month after the last treatment session

Method of measurement

Manual assessment with the Oxford scale

4

Description

Strength and endurance of pelvic floor muscles

Timepoint

Before and after the intervention and one month after the last treatment session

Method of measurement

Biofeedback

Intervention groups

1

Description

Control group: This group receives only routine exercises to strengthen the pelvic floor muscles, each session is 30 minutes and is divided into three parts: 1) Sustained contractions: Patients complete pelvic muscle contraction for 6-10 seconds each time, then start the next contraction after 10 seconds rest, 8-10 repetitions per set, 1-2 sets per session. 2)Phasic contractions: Patients complete pelvic muscle contraction for 2-5 seconds each time, then rest, rest time is twice the contraction time, 10 repetitions per set, 1-3 sets per session. 3) Guided training: Patients are asked to simulate activities such as coughing, sneezing while contracting the pelvic floor muscles. Treatment sessions will be held in 3 sessions per week for a total period of 3 weeks.

Category

Rehabilitation

2

Description

First intervention group: Pelvic floor muscle strengthening exercises with biofeedback : The treatment program includes 9 sessions of combined pelvic floor rehabilitation, that is, the combination of electromyographic biofeedback and progressive exercises of the pelvic floor muscles, will be used as a therapeutic exercise program. Biofeedback takes 15 minutes. A special vaginal probe of Leukoplast combination, which is the same for all patients, will be used for electromyographic biofeedback applications. Each probe will be unique to the patient. The patient will be given the necessary training to train the pelvic floor muscles alone and using vaginal cones in treatment sessions. According to the Kegel treatment protocol, 300 contractions are performed daily. Contraction of the pelvic floor by maintaining the vaginal cone while standing, lying down, sitting and going up and down the

stairs as well as running will be done gradually at home with daily progress. Each patient's in-person treatment session will take 45 minutes to one hour. The treatment sessions will be performed 3 times a week for a total period of 3 weeks.

Category

Treatment - Devices

3

Description

Second intervention group: Repetitive Transcranial Magnetic Stimulation (rTMS) : All participants use the same rTMS device, which has a figure-of-eight coil with the handle facing the sensorimotor cortex on one side. The physiotherapist chooses the pelvic floor muscle as the reference muscle for applying rTMS, and rTMS is applied to the Supplementary Motor Area (SMA) which corresponds to the pelvic floor muscles. Patients are positioned in the supine position and inhibitory rTMS is used for this group of patients on the SMA for 20 minutes each time. LF-rTMS is a inhibitory protocol consisting of 1 pulse per second applied continuously (2000 pulses in total). Treatment sessions will be held in 3 sessions per week for a total period of 3 weeks.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Maryam Miri Torbaghan

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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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
There is no more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available