

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the Combined Effect of Stability Exercises and Interference Current in Improving Maximal Intravaginal Pressure, Frequency of Urinary Incontinence, and Quality of Life in Women with Stress Urinary Incontinence

Protocol summary

Study aim

To compare the effects of stability exercises (with emphasis of pelvic floor muscles) combined with interferential currents versus the same stability exercises alone on improving intravaginal pressure, incontinence rate, quality of life (UI_SF ICIQ questionnaire) in the management of women with stress urinary incontinence.

Design

A single-blind randomized controlled trial with parallel-group with controlled group will be performed on 22 women with stress urinary incontinence. The www.sealedenvelope.com website will be used for randomization.

Settings and conduct

Patients will be visited in the Ghaem physiotherapy clinic, Mashhad, Iran. The patients will be reviewed by the principal investigator in terms of inclusion and exclusion criteria. The patients will be examined by the assessor who is blinded to the patient's label. Finally, the treatment will be started by the physiotherapist. The physiotherapist was blinded to patients allocation. In the control group, the patients will receive stability exercises and interference currents, no output will be used.

Participants/Inclusion and exclusion criteria

Patients with mild and severe stress urinary incontinence without any other significant urogenital disorders.

Intervention groups

Both groups are examined one week after the inclusion and exclusion criteria and then, the intervention group receives a combination of stabilization exercises 3 times a week for 4 weeks with emphasis on the pelvic floor muscles and interference current. The control group is given stabilization exercises 3 times a week for 4 weeks with emphasis on the pelvic floor muscles along with the placebo interference current. Both groups receive educational pamphlets

Main outcome variables

Maximum intravaginal pressure and duration of maintenance, number of incontinences, quality of life and score of ICIQ_UI SF questionnaire

General information

Reason for update

To improve the precision of the results and enhance the study power, the sample size was increased to 15 participants per group.

Acronym

IRCT registration information

IRCT registration number: **IRCT20161221031506N9**

Registration date: **2022-07-10, 1401/04/19**

Registration timing: **prospective**

Last update: **2025-08-29, 1404/06/07**

Update count: **1**

Registration date

2022-07-10, 1401/04/19

Registrant information

Name

Salman Nazary-Moghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-06, 1401/05/15

Expected recruitment end date

2023-07-19, 1402/04/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Combined Effect of Stability Exercises and Interference Current in Improving Maximal Intravaginal Pressure, Frequency of Urinary Incontinence, and Quality of Life in Women with Stress Urinary Incontinence

Public title

Comparing the Combined Effect of Stability Exercises with Emphasis on Pelvic Floor Muscles and Interference Current on Improving the symptoms of Women with Stress Urinary Incontinence

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Have experienced stress urinary incontinence at least twice a week for two weeks. Stress urinary incontinence was confirmed by urodynamic tests and clinical examination. Mild and moderate stress urinary incontinence No history of taking anticholinergic drugs and other drugs during physiotherapy period.

Exclusion criteria:

smoking Known types of neuropathy Virginity Pregnancy and lactation History of pelvic surgery in the past year History of reconstructive surgery in the genitourinary system Having a urinary tract infection Chronic asthma and cough (more than three months) Having perceptual problems and mental illness based on a doctor's examination History of genitourinary neoplasia History of abnormalities in the genitourinary system Having any type of urinary incontinence other than pure stress urinary incontinence Severe stress urinary incontinence Severe prolapse Urethral hyper mobility Intrinsic sphincter dysfunction Severe neuromuscular disorders that compromise exercise performance

Age

To 65 years old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

The random numbers is prepared using the website www.sealedenvelope.com in terms of 1 and 2. The 22 cards (taking into account 20% dropout) is placed into sealed envelopes. After the evaluation, the patients selected the card according to the order placed in the envelope. If the number of 1 is observed, the patient will be included in the intervention group, and if the number of 2 is observed, the patients will be included in the control group. Another physiotherapist who is not aware about the allocation process will evaluate the patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

The outcome assessor and the statistical analyzer will be blinded to the group allocation. The patient will receive a placebo interferential current. The outcome assessor will evaluate the patients in a separate room. She has not any information regarding the patient group. In addition, statistical analysis will be blinded to group allocation. In the spss file, codes a, and b will be defined for intervention and control groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

The Ethics Committee of Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Science's Research and Development Deputy Office, Across 18th University Street, University Street.

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Province

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Postal code

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Approval date

2022-06-28, 1401/04/07

Ethics committee reference number

IR.MUMS.FHMPM.REC.1401.062

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

Stress urinary inconvenience

ICD-10 code

N39.3

ICD-10 code description

Stress incontinence (female) (male)

Primary outcomes

1

Description

Mean maximum intravaginal pressure

Timepoint

Immediately after allocation into , 4 and 8 weeks after starting treatment

Method of measurement

Pressure biofeedback

2

Description

Quality of life

Timepoint

Immediately after allocation into , 4 and 8 weeks after starting treatment

Method of measurement

ا_QOL توسط پرسشنامه

3

Description

ICIQ_UI SF questionnaire score

Timepoint

Immediately after allocation into , 4 and 8 weeks after starting treatment

Method of measurement

ICIQ_UI SF questionnaire

4

Description

Duration of maintenance of maximum intravaginal pressure

Timepoint

Immediately after allocation into , 4 and 8 weeks after starting treatment

Method of measurement

Pressure biofeedback

5

Description

Frequent urinary incontinence for a week

Timepoint

Immediately after allocation into , 4 and 8 weeks after starting treatment

Method of measurement

With bladder diary

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: They will receive 12 sessions of interferential currents 4 weeks, 3 times per week. The intensity of the interferential currents causes the related contractions. Electrodes placement will be done bipolarly and by the Dumoulin method. Then, the patients will be performed the stability exercises. The patients in this group should perform the stability exercises for 4 weeks, 5 times per week. It should be noted that three out of five times will be performed under the physiotherapist' supervision. Generally, the duration of the exercises is 30 minutes per session. The patients should repeat each exercise 10-20 times in the requested positions. In the first session, people will be given exercise booklets, which contain pictures of the prescribed exercises. The patients should record their performed exercises during the week. The participants in the intervention group are trained to perform stability exercises while exhaling. Individuals are also asked to do diaphragmatic breathing for 3-4 minutes before starting stability exercises. This improves the blood circulation of the intestines and improves the function and rhythm of the pelvic floor muscle. Also, patients should have diaphragmatic breathing during rest periods between exercises.

Category

Rehabilitation

2

Description

Control group: Similarly, the intervention group performs stabilization exercises 5 times a week for 4 weeks, 3 of which are performed under the supervision of a physiotherapist after receiving the placebo interference current, and the other 2 times are performed at home. Everyone is given an educational pamphlet

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem physiotherapy clinic

Full name of responsible person

Reyhane Sekandari

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Narjes building, first floor, Physiotherapy Department, Qaem Hospital, Nurse Street, Mashhad, Iran

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Sponsors / Funding sources

1

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Grant name
Personal Grant (Dr Salman Nazary-Moghadam)
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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

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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

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

All data will be reported in the form of a research article.
Raw data will be delivered to researchers for meta analysis

When the data will become available and for how long

6 months after publication

To whom data/document is available

برای پژوهشگران

Under which criteria data/document could be used

For meta-analysis Only.

From where data/document is obtainable

Nazary_salman@yahoo.com

What processes are involved for a request to access data/document

The response will be sent 3 within months after considering the researcher's request.

Comments