Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 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-groupwith 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.
City
Mashhad
Province
Razavi Khorasan
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

I_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 torelated 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 patienrts 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 floormuscle. Also, patients should have diaphragmatic breathing during rest periods betwwen 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

Street address

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

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Sponsors / Funding sources

1

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Name of organization / entity
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Full name of responsible person
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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
Name of organization / entity
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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 analys
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