Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Extraction of Muscle Synergies to Investigate Changes in Biomechanical Parameters after the Addition of Abdominal Hypopressive Technique to Pelvic Floor Muscle Training in Women with Urinary Incontinence

Protocol summary

Study aim

Determining the synergy of the pelvic floor and abdominal muscles due to the addition of hypopressive abdominal training to the routine pelvic floor muscle training in women with stress urinary incontinence

Design

A randomized controlled clinical trial with two parallel intervention groups and one control group, triple-blind study on 78 individuals, randomized by Matlab code 'randi'

Settings and conduct

Patients will be randomly entered into the intervention groups. Initial assessment will be done. After a total of 10 training sessions, the final assessment will be performed. The healthy control group has only an initial assessment. Patients, researchers, and analyzers will be blinded to the intervention groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: women with stress urinary incontinence, Age between 25 and 50 years, married, leak at least three times a week, ICIQ-UI-SF questionnaire score equal to or greater than 5. Exclusion criteria: pregnancy, menopause, POP > 2, Oxf < 3, Res > 50 ml, history of cancer, pelvic surgery, overactive bladder, hormone therapy, urinary tract infection, low back pain in the last 3 months, or other diagnosed neurologic diseases.

Intervention groups

Group 1: Women with stress incontinence receiving routine pelvic floor training. Group 2: Women with stress incontinence receiving pelvic floor training + low abdominal training. Control group: Women without complaints of urinary incontinence.

Main outcome variables

Time and frequency-domain parameters of the pelvic floor and abdominal muscles' electromyography; muscular synergy matrices; intra-abdominal and vaginal pressures; scores of ICIQ-UI SF, ICIQ-LUTS QOL, and BROOME questionnaires.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210702051761N1**
Registration date: **2021-07-23, 1400/05/01**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-23, 1400/05/01**
Update count: **0**

Registration date

2021-07-23, 1400/05/01

Registrant information

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Masumeh Babayi
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Extraction of Muscle Synergies to Investigate Changes in Biomechanical Parameters after the Addition of Abdominal Hypopressive Technique to Pelvic Floor Muscle Training in Women with Urinary Incontinence

Public title
Extraction of Muscle Synergies after Pelvic Floor Muscle Training in Women with Urinary Incontinence
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Stress Urinary Incontinence (SUI) with at least 3 leaks per week ICIQ-UI SF Score >= 5 Married
Exclusion criteria:
Pregnancy Menopause History of cancer History of pelvic surgery POP > 2 OGS < 3 Having Over Active Bladder (OAB) PVR > 50 ml History of hormone therapy Urinary tract infection Low Back pain in the last 3 months Any known disease of the nervous system
Age
From **25 years** old to **50 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **78**
Randomization (investigator's opinion)
Randomized
Randomization description
Random numbers will be generated between 1 and 52 by using a computer algorithm (matlab code: randi) to specify two intervention groups (1 and 2, each group owns 26 participants). The numbers will be kept in concealed envelopes. Patients, researchers, and analyzers will not be aware of what intervention has been applied to the participants.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The patient is explained that there are two types of intervention, but the person is not informed of her assigned group. The patient is initially evaluated by a researcher (blind) before assigning the group. At the end of the initial evaluation, the patient chooses a concealed envelope and delivers it to the research assistant. In this way, the patient identifies the group itself but is not aware of the results of randomization. The clinical assistant teach the home exercises and explains the training sessions based on the intervention group that she is in. At the end of the intervention, the researcher performs the final evaluation of the patient without knowing the treatment the patient has received. The analyzer which is blind to the intervention group using coded results performs the output analyses. The healthy control group does not need to be blind, as they are not patient and do not receive any intervention, and, only have an initial evaluation. The blindness of the participants means blindness of the patients who all receive interventions.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Tabriz University of Medical Sciences
Street address
Central Building of Tabriz University of Medical Sciences, Golgasht Street
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East Azarbaijan
Postal code
5165665931
Approval date
2021-07-05, 1400/04/14
Ethics committee reference number
IR.TBZMED.REC.1400.311

Health conditions studied

1

Description of health condition studied
Stress Urinary Incontinence
ICD-10 code
N39.3
ICD-10 code description
Stress incontinence (female) (male)

Primary outcomes

1

Description
Electromyography of the pelvic floor and abdominal muscles
Timepoint

Before and after the interventions

Method of measurement

Electromyogram

2

Description

Intra-abdominal and vaginal pressures

Timepoint

Before and after the interventions

Method of measurement

Pressure sensor probe

3

Description

scores of ICIQ-UI SF, ICIQ-LUTS QOL and BROOME questionnaires

Timepoint

Before and after the interventions

Method of measurement

ICIQ-UI SF, ICIQ-LUTS QOL and BROOME questionnaires

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Pelvic floor muscle training will be performed for 12 weeks, once a week supervised by a physiotherapist and every day of the week at home. The exercises consist of 10 progressive stages that will progress one stage per week. It takes two weeks for people to reach the level expected by the researcher. The exercises include stretching exercises (15-30 seconds each) and strengthening exercises (10-12 seconds). The rest time between each contraction is 10-12 seconds. During the treatment process, continuous and slow breathing is performed. Pelvic floor contraction is similar to a condition in which a person is asked to stop urinating while urinating. Each exercise is repeated three sets a day and each set 10 times.

Category

Rehabilitation

2

Description

Intervention group: Pelvic floor muscle training + abdominal hypopressive technique (AHT) that in addition to receiving the full protocol of the first group, will also receive AHT exercises with Caufriez technique for 12 weeks. At the familiarization session, participants will be provided with information on the location and function of the PFM and TrA muscle. They are taught how to contract their PFM and TrA exclusively. Then, how to do AHT is taught; By first performing a slow diaphragmatic inhalation, followed by a general exhalation with closed glottal pathway, which is accompanied by a gradual contraction of the abdominal wall muscles with diaphragmatic aspiration. The person is also taught how to contract their PFM in different positions at the same time as the diaphragm aspiration. The number of sessions and their durations are the same as the previous intervention group.

Category

Rehabilitation

3

Description

Healthy control group: without any intervention, only participated for initial assessments

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Masumeh Babayi

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Sponsors / Funding sources

1

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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
Sahand University of Technology
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)
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
Yes - There is 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
All processed and analyzed data will be released. These data include the questionnaire scores and linear and nonlinear outcomes of the stability, before and after the interventions.
When the data will become available and for how long
from 6 months after the official publication of results
To whom data/document is available
All academic and clinical researchers
Under which criteria data/document could be used
Only for therapeutical applications and use in neuro-

musculoskeletal simulations

From where data/document is obtainable

By contacting the corresponding author of the published papers by email, phone or postal address

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

Process: 1. Determining the data of interest by the applicant 2. contacting the corresponding author to submit the queries by the applicant 3. Reviewing the queries by the research team 4. Responding to the queries till 10 working days by the research team

Comments