

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Name

Masumeh Babayi

Name of organization / entity

Sahand University of Technology

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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

AgeFrom **25 years** old to **50 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample sizeTarget 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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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

Sponsor

Name of organization / entity

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Full name of responsible person

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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****Name of organization / entity**

Sahand University of Technology

Full name of responsible person

Masumeh Babayi

Position

PhD Student

Latest degree

Master

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

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