Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the Effects of Isolated Pelvic Floor Muscles Training, Deep Abdominal Muscles Training and Their Combination in Quality of Life of Females with Stress Urinary Incontinence.

Protocol summary

Summary

The aim of this study is to investigate the effects of pelvic floor muscles (PFM) training, deep abdominal muscles training and their combination on the quality of life of females with stress urinary incontinence (SUI). This study is a double – blind (subjects and examiners), randomized controlled trial. 54 females with SUI will be included in this study. Subjects will be excluded if they have a history of surgery involving the pelvic floor; neurological or psychiatric disease or a major medical condition, current pregnancy or less than 3 months postpartum and prolapse. Patients will be randomly assigned into 3 treatment groups; the first group receives a conventional treatment with focus of the PFM, the second group will perform only transverse abdominal (TrA) muscle exercises and third; cocontraction of both PFM and TrA. Exercises progress from simple to functional. Physiotherapist will instruct and monitor exercises 1 day a week and will check exercises using telephone calls twice a week for 8 weeks. To record the quality of life, Incontinence Quality of Life (I-QOL) Questionnaire and to access maximal voluntary contraction (MVC) and endurance of pelvic floor muscles perinometer will be used before and after treatment interventions. Main outcome measures such as I-QOL scale, MVC and endurance of PFM will be reported.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082218362N2**
Registration date: **2017-10-19, 1396/07/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-10-19, 1396/07/27

Registrant information

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2017-07-24, 1396/05/02

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effects of Isolated Pelvic Floor Muscles Training, Deep Abdominal Muscles Training and Their Combination in Quality of Life of Females with Stress Urinary Incontinence.

Public title

Comparison of the Effects of Isolated Pelvic Floor Muscles

Training, Deep Abdominal Muscles Training and Their Combination in Management of Stress Urinary Incontinence.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: Females with SUI in the age range of 18-60 years will be included in this study if they have complaint of involuntary leakage of urine on effort or on sneezing or coughing. Exclusion Criteria: Subjects will be excluded if they have a history of surgery involving the pelvic floor; neurological or psychiatric disease or a major medical condition; current pregnancy or less than 3 months postpartum; prolapse; severe low back pain or pelvic pain; ongoing urinary tract infections and undergoing concurrent treatment for SUI.

Age
From **18 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Table of random numbers will be used to simply assign the subjects in three groups of treatment. The examiner will not be aware of which intervention will be administered to which subject. The patients do not aware of other groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address
Central Office, University Campus, Golestan

City
Ahvaz

Postal code

Approval date
2017-07-22, 1396/04/31

Ethics committee reference number
IR.AJUMS.REC.1396.453

Health conditions studied

1

Description of health condition studied
stress urinary incontinence

ICD-10 code
N39.3

ICD-10 code description
Stress incontinence

Primary outcomes

1

Description
Incontinence Quality of Life Questionnaire scale

Timepoint
Before and after treatment interventions

Method of measurement
Incontinence Quality of Life Questionnaire

Secondary outcomes

1

Description
maximal voluntary contraction of pelvic floor muscles

Timepoint
Before and post treatment intervention

Method of measurement
perinometer

2

Description
endurance of pelvic floor muscles

Timepoint
Before and post treatment intervention

Method of measurement
perinometer

Intervention groups

1

Description
Intervention 1: Participants in the pelvic training group will be instructed to contract PFM .Vaginal palpation will be applied for the valid evaluation of vaginal squeeze pressure. Contraction of PFM will be progressed by positioning in: 1st session: crook; 2nd: supine; 3rd: side lying; 4th: sitting; 5th: standing; 6th, 7th: walking and last: ADL. Individuals will meet physiotherapist once a week to be instructed new exercise and physiotherapist will check exercises using telephone calls twice a week for 8 weeks. Participants will perform exercises 3 sets, 2 times a day .Each set contains 10 repetition of isolated

MVC of PFM as long as possible (maximum: 10 seconds) and 5 fast contraction(contraction: 1 second, rest:1second).

Category

Rehabilitation

2

Description

Intervention 2: Participants in the deep abdominal muscles training group will be instructed to contract Transversus Abdominis. Contraction of TrA will be progressed by positioning in: 1st session: crook; 2nd: crook with flexion and extension of knee; 3rd: crook with flexion and extension of shoulder; 4th: sitting; 5th: standing; 6th, 7th: walking and last: ADL. Individuals will meet physiotherapist once a week to be instructed new exercise and physiotherapist will check exercises using telephone calls twice a week for 8 weeks. Participants will perform exercises 3 sets, 2 times a day .Each set contains 10 repetition of isolated maximum voluntary contraction of TrA as long as possible (maximum: 10 seconds) and 5 fast contraction (contraction: 1 second, rest:1second).

Category

Rehabilitation

3

Description

Intervention 3 : Participants in the combination of pelvic and abdominal muscles training group will be instructed to contract PFM and TrA. Vaginal palpation will be applied for the evaluation of vaginal squeeze pressure. Cocontraction of PFM and TrA will be progressed by positioning in: 1st session: crook; 2nd: supine; 3rd: side lying; 4th: sitting; 5th: standing; 6th, 7th: walking and last: ADL. Individuals will meet physiotherapist once a week to be instructed new exercise and physiotherapist will check exercises using telephone calls twice a week for 8 weeks. Participants will perform exercises 3 sets, 2 times a day .Each set contains 10 repetition of isolated maximum voluntary Cocontraction of PFM and TrA as long as possible (maximum: 10 seconds) and 5 fast contraction (contraction: 1 second, rest:1second).

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rehabilitation Clinics of School of Rehabilitation Sciences, Ahvaz Jundishapur University of Medica

Full name of responsible person

Dr. Fateme Esfandiarpour

Street address

School of Rehabilitation Sciences, University Campus, Golestan

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences, Vice Chancellor for Research Development and Techn

Full name of responsible person

Dr. Behzad Sharif Makhmalzadeh

Street address

The office of Vice Chancellor for Research Development and Technology, University Campus, Golestan

City

Ahvaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz Jundishapur University of Medical Sciences, Vice Chancellor for Research Development and Techn

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty