

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effectiveness of Tele-rehabilitation for supervised pelvic floor motor learning exercise with biofeedback in subjects with stress urinary incontinence (SUI)

Protocol summary

Study aim

The purpose of this study is to evaluate the effectiveness of Tele-rehabilitation on stress urinary incontinence and patients' satisfaction with this method.

Design

Two arm parallel group randomized trial with block randomization

Settings and conduct

Referrals to private physiotherapy centers in Tehran and Karaj. Pelvic floor muscle exercises are based on Tele-rehabilitation. To transmit data simultaneously from distance and benefit the patient from the effects of biofeedback, a pressure biofeedback device will be used. During a month of training, the number of biofeedback sessions is reduced over time to reduce dependence on external feedback and be replaced by internal feedback during the motor learning process.

Participants/Inclusion and exclusion criteria

Inclusion criteria: women aged 20 to 50 years, able to use lap-tops or computer, diagnosed with stress urinary incontinence (SUI) only; exclusion criteria: pregnancy, delivery within past 6 months, immobility, pelvic organ prolapse grades 3 and 4, diagnosed with any neurologic condition, received other treatments for SUI

Intervention groups

Control group: Training motor learning exercises using biofeedback with physiotherapist near the patient
Intervention group: Training motor learning exercises using biofeedback with physiotherapist's remote supervision

Main outcome variables

Pelvic floor muscle strength, endurance and neuromuscular coordination; Quality of life using I-QOL and ICIQ-SF questionnaires; Patient satisfaction using MRPS questionnaire; number of urine leakage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211121053129N1**

Registration date: **2021-12-01, 1400/09/10**

Registration timing: **prospective**

Last update: **2021-12-01, 1400/09/10**

Update count: **0**

Registration date

2021-12-01, 1400/09/10

Registrant information

Name

Zahra Tajbakhsh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7749 6433

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-11, 1400/09/20

Expected recruitment end date

2022-06-10, 1401/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Tele-rehabilitation for supervised pelvic floor motor learning exercise with biofeedback in subjects with stress urinary incontinence (SUI)

Public title

The effect of Tele-rehabilitation on stress urinary incontinence

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged between 20 to 50 years Able to use lap-top or computer Diagnosed with stress urinary incontinence only

Exclusion criteria:

Pregnancy Delivery within the past six months Immobility Grades 3 or 4 pelvic organ prolapse Diagnosed with any neurologic condition Having received other treatments for stress urinary incontinence

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization. The main idea of block randomization is that patients are divided into m blocks. Each block is randomly chosen in order to put n patients in A group and n patients in B group. This method ensures equal treatment allocation within each block if a complete block is used. We select 10 blocks consisting of 4 patients. An equal number of people are assigned to each group in each block. The block randomization method is designed to randomize the distribution of individuals to the study groups so that the sample size of the groups is equal. This method is used to ensure balance in sample size between groups over time. We will identify 10 blocks with 4 patients in each block, two patients in group A (intervention) and two patients in group B (control), and then randomization will be applied to both blocks in the intervention group and the control group. For example, when a participant enters a study, she is asked to select a block from 1 to 10 and then A or B. When one person selects a block, the order of the other three items is randomly defined.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of university of social welfare and rehabilitation sciences

Street address

University of social welfare and rehabilitation sciences, Kudakyar Ave., Daneshju Blvd.

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Province

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Postal code

1985713834

Approval date

2021-11-20, 1400/08/29

Ethics committee reference number

IR.USWR.REC.1400.211

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

International consultation on incontinence questionnaire-short form score

Timepoint

International consultation on incontinence questionnaire-short form score will be field at baseline (before the intervention) and again at the end of the intervention

Method of measurement

International consultation on incontinence questionnaire-short form

2

Description

Number of urine leakage

Timepoint

Number of urine leakage will be recorded at baseline (before the intervention) and again at the end of the intervention

Method of measurement

Number of urine leakage will be recorded according to

the patients' answer to first question in International consultation on incontinence questionnaire-short form

3

Description

Incontinence-quality of life questionnaire score

Timepoint

Incontinence-quality of life questionnaire score will be field at baseline (before the intervention) and again at the end of the intervention

Method of measurement

Incontinence-quality of life questionnaire

Secondary outcomes

1

Description

Pelvic floor muscle strength

Timepoint

Pelvic floor muscle strength will be evaluated once before the intervention and again at the end of the intervention

Method of measurement

Perineometer

2

Description

Pelvic floor muscle endurance

Timepoint

Pelvic floor muscle endurance will be evaluated once before the intervention and again at the end of the intervention

Method of measurement

Perineometer

3

Description

Pelvic floor muscle neuromuscular coordination

Timepoint

Pelvic floor muscle neuromuscular coordination will be evaluated once before the intervention and again at the end of the intervention

Method of measurement

Perineometer

4

Description

Patient satisfaction score according to The MedRisk instrument for measuring patient satisfaction with physical therapy care score

Timepoint

The MedRisk instrument for measuring patient satisfaction with physical therapy care score will be field after the intervention.

Method of measurement

The MedRisk instrument for measuring patient satisfaction with physical therapy care

Intervention groups

1

Description

Intervention group: Participants are remotely supervised and operate the biofeedback device themselves. The treatment program will be done in 4 weeks and 14 sessions. 4 sessions will be held in the first and second week and 3 sessions in the third and fourth week each. The protocol consists of: endurance training, strength training, motor-control and motor-learning training. The duration of holding the slow contraction in endurance training will be 6 to 8 seconds and will be done for 3 sets of 10 repetitions. Immediately after the endurance contraction, rest is given for the duration of the contraction. Strength contraction will include 4 rapid contractions. Rapid contraction lasts for 2 seconds at maximum voluntary contraction followed by 2 seconds of rest. In each session, each contraction will be repeated and practiced in the supine, sitting, and standing positions, and after the patient has been able to perform the contractions correctly, these contractions will be coordinated with the movements of the upper and lower limbs.

Category

Rehabilitation

2

Description

Control group: The physiotherapist is present next to the patient. The treatment program will be done in 4 weeks and 14 sessions. 4 sessions will be held in the first and second week and 3 sessions in the third and fourth week each. The protocol consists of: endurance training, strength training, motor-control and motor-learning training. The duration of holding the slow contraction in endurance training will be 6 to 8 seconds and will be done for 3 sets of 10 repetitions. Immediately after the endurance contraction, rest is given for the duration of the contraction. Strength contraction will include 4 rapid contractions. Rapid contraction lasts for 2 seconds at maximum voluntary contraction followed by 2 seconds of rest. In each session, each contraction will be repeated and practiced in the supine, sitting, and standing positions, and after the patient has been able to perform the contractions correctly, these contractions will be coordinated with the movements of the upper and lower limbs.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

University of social welfare rehabilitation sciences

Full name of responsible person

Zahra Tajbakhsh

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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

University of social welfare and rehabilitation 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**

University of social welfare and rehabilitation sciences

Full name of responsible person

Zahra Tajbakhsh

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

University of social welfare and rehabilitation sciences

Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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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

Only part of the individual data of the study participants, such as information about the main outcome or the like, can be shared

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions and also People who are in the industry can apply for them.

Under which criteria data/document could be used

If necessary, the results and data can be provided without mentioning the name.

From where data/document is obtainable

Contact the researchers to receive the required documents or data. Contact information: E-mail: zah.tajbakhsh@uswr.ac.ir tshzahra@yahoo.com Phone number: 09022073102 address: University of social welfare and rehabilitation sciences, Kudakyar Ave., Daneshju Blvd.,Evin

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

Request from the researchers and obtain permission from the university

Comments