Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 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)

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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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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
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Sponsors / Funding sources

1

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Full name of responsible person
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https://researchdeputy.uswr.ac.ir/index.jsp?fkeyid=&siteid=56&pageid=15376
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
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Position
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Person responsible for updating data

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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