Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Co-effect of the Sensate Focus Technique and Pelvic Floor Muscle Exercises on the SexualFunction in Married Women with Stress Urinary Incontinence (SUI).

Protocol summary

Study aim
Determining the effect of simultaneous sensory focus training and pelvic floor exercises on the sexual function of married women with stress urinary

Design
Randomized controlled clinical trial with parallel groups, double-blind, randomized, on 60 patients. For randomization due to the two-group nature of the study, there were six different modes for blocks of 4, then selecting random numbers between one and 6 and finally specifying the intervention allocation list based on the previous random numbers (BABA-BBAA-AABB-….) was carried out and opaque envelopes in the package numbered in order were used to conceal the allocation. After collecting the data, they will be analyzed using SPSS version 22 software.

Settings and conduct
This study investigates the effect of sensory focus techniques and pelvic floor exercises on eligible women in obstetrics and gynecology clinics in Qom and Tehran. In this study, written consent forms and demographic and fertility questionnaires will be collected from women, and then their pelvic floor muscles will be assessed. Participants will be randomly divided into two intervention and control groups, and both groups will be monitored by the researcher, and the researcher and participants will be blinded.

Participants/Inclusion and exclusion criteria
Married Iranian women Having had sexual intercourse in the last 8 weeks Conditions of non-entry:Having an underlying disease Unmarried

Intervention groups
In the intervention group, an in-person training session will be conducted in the form of theoretical training on sensory focus techniques and pelvic floor exercises, along with presentation of slides and educational videos. The control group will only be trained on pelvic floor exercises.

Main outcome variables
Sexual function; Pelvic floor muscle condition.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240821062824N1**
Registration date: **2025-02-24, 1403/12/06**
Registration timing: **prospective**

Last update: **2025-02-24, 1403/12/06**
Update count: **0**

Registration date
2025-02-24, 1403/12/06

Registrant information

Name
Seyedeh fatemeh Naqavi
Name of organization / entity
Tarbiat Modares University
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-02-28, 1403/12/10

Expected recruitment end date
2025-04-30, 1404/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Co-effect of the Sensate Focus Technique and Pelvic Floor Muscle Exercises on the SexualFunction in Married Women with Stress Urinary Incontinence (SUI).

Public title

The Co-effect of the Sensate Focus Technique and Pelvic Floor Muscle Exercises on the SexualFunction in Married Women with Stress Urinary Incontinence (SUI).

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian married women Having sex in the last 8 weeks No known underlying disease other than stress urinary incontinence. Not having a mental illness. Husband's monogamy and living with spouse currently and during the study. Persian language reading and writing skills The couple's lack of addiction to drugs and alcohol No stressful event within the past month No history of pelvic floor surgery. Not taking medications that affect sexual function

Exclusion criteria:

Having underlying diseases Unmarried

Age

From **18 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

This study will be a randomized controlled clinical trial. The study units will be 60 married women eligible for the study who will be invited to the office following a telephone call from the researcher. After marrying women with stress urinary incontinence refer to the clinic, the research units will explain the objectives, confidentiality of responses, providing general information, and autonomy at each stage of the study. After obtaining written informed consent, they will be asked to complete the demographic fertility questionnaires and the FSFI questionnaire. The researcher will assess the pelvic floor muscles using the pelvic floor muscle assessment checklist (modified Oxford scoring system). The subjects will be instructed to complete the urinary event recording table 24 hours a day until the end of the intervention period. In the second stage, subjects will be divided into intervention and control groups using a block randomization method using four-person random blocks, in such a way that the block list will be written and numbers will be assigned to them. Due to the two-group study, there were six different modes for the four-person blocks, so random numbers between one and six were selected and finally the intervention allocation list was determined based on the random numbers (BABA-BBAA-AABB-....) will be conducted. Opaque envelopes in a numbered order will be used to conceal the allocation. The researcher will randomly select the envelopes and then enter the research units into the sampling system in order. In the intervention group, an in-person training session will be held in the form of theoretical training on sensory focus techniques and pelvic floor exercises, along with the presentation of slides and educational videos. This two-hour workshop will be held individually in a room confidentially and quietly, and a step-by-step guide to sensory focus exercises and pelvic floor exercises will be provided to the samples. One month later and two months later, the research units will be contacted to come for evaluation and, if necessary, further explanations will be provided to them and their questions will be answered.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding will be done on participants and researcher.The research units are divided into two intervention and control groups using block randomization method and using random blocks of four, in such a way that the list of blocks is written and numbers are assigned to them. According to the two-group study, there were six different modes for the blocks of four, so random numbers between one and six were selected and finally the intervention allocation list is determined based on random numbers (BABA-BBAA-AABB-....). To hide the allocation, opaque envelopes are used in numerical order. The researcher randomly selects the envelopes and then enters the research units into the sampling system in order.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tarbiat Modares University

Street address

No. 53, Shahrivar Street, North Amirabad, Tehran

City

Tehran

Province
Tehran
Postal code
۱۴۱۱۷۱۶۹۱۱
Approval date
2025-01-25, 1403/11/06
Ethics committee reference number
IR.MODARES.REC.1403.150

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
SexualFunction
Timepoint
Sexual function will be assessed by the researcher at the beginning of the study (before the intervention) and repeated 1-2 months after the intervention.
Method of measurement
Sexual function will be assessed by the researcher at the beginning of the study (before the intervention) using the FSFI questionnaire and will be repeated 1-2 months after the intervention.

Secondary outcomes

1

Description
Pelvic floor muscle strength
Timepoint
Before the start of the intervention, 1 month and 2 months after the start of the intervention.
Method of measurement
Pelvic floor muscle assessment checklist

Intervention groups

1

Description
Intervention group: In the second stage, after randomly dividing the subjects into intervention and control groups, an in-person training session will be held in the intervention group in the form of theoretical training on sensory focus techniques and pelvic floor exercises, along with slides and educational videos. This two-hour workshop will be held individually in a room in a confidential and quiet manner, and a step-by-step guide to sensory focus exercises and pelvic floor exercises will also be made available to the samples. One month later and two months later, the research units will be contacted to come for evaluation and, if necessary, further explanations will be provided to them and their questions will be answered. The contact numbers and addresses of the participants will be recorded for access to the samples and follow-up assessments, and the researcher's contact number will also be made available to the samples to answer any possible questions. In the third stage, following the intervention, the researcher will contact the research units in the intervention group every week to ensure that sensory focus exercises and pelvic floor exercises are performed. The evaluation of the research units will be conducted in person 1 and 2 months after the intervention by completing the aforementioned questionnaires. If any side effects related to the exercises are observed, the relevant side effects will be recorded and necessary follow-up will be carried out.
Category
N/A

2

Description
Control group: In the second stage, after dividing the subjects into intervention and control groups by block randomization, the control group will only be taught pelvic floor exercises along with slides and educational videos, and a step-by-step guide to pelvic floor exercises will be provided to the samples. One month later and two months later, the research units will be contacted to come for evaluation and, if necessary, further explanations will be given to them and their questions will be answered. The contact number and address of the participants will be recorded for access to the samples and follow-up evaluations, and the researcher's contact number will also be available to the samples to answer any possible questions. At the end of the evaluation period, the control group will be provided with a sensory focus exercise educational booklet, and if they wish, an in-person sensory focus exercise educational session will also be held for them. If any side effects related to the exercises are observed, the relevant side effects will be recorded and the necessary follow-up will be carried out.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Obstetrics and gynecology office
Full name of responsible person
Doctor Narjes, Nayeb-Hashemi
Street address
Ground floor Jalil Karimi Alley, No.1, next to the Road Department, between Khaghani intersection Narmak 30-meter intersection, Damavand Street, Tehran.

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Sponsors / Funding sources

1

Sponsor
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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
Tarbiat Modares University
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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Sayyed Fatemeh Naqavi
Position
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Latest degree
Bachelor
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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
Undecided - It is not yet known if there will be 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
Part of the data, such as information related to the questionnaire file

When the data will become available and for how long
"Access period begins 6 months after results are published."

To whom data/document is available
Researchers working in academic and scientific institutions.

Under which criteria data/document could be used
It is permitted if used for reference and the source is cited.

From where data/document is obtainable
Researcher naghavi.fatemeh@modares.ac.ir

What processes are involved for a request to access data/document
After sending the email requesting the documents, they will be sent after reviewing the matter.

Comments