Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effects of Yoga and Transcutaneous Tibial Nerve Stimulation on Stress, Anxiety, and Depression Levels, Quality of Life, Pelvic Floor Muscle Function, and Urinary Incontinence Symptoms in Women with Urgency Urinary Incontinence

Protocol summary

Study aim
To compare the effects of yoga therapy, transcutaneous tibial nerve stimulation (TTNS), and combined yoga therapy and TTNS on stress, anxiety, depression, quality of life, pelvic floor muscle function, and urinary incontinence symptoms in women with urgency urinary incontinence

Design
Randomized, single-blind, parallel-group trial (no control), 70 women with urgency urinary incontinence. Block randomization (size 6) via randomization.com.

Settings and conduct
Participants will be identified via the Physiotherapy Clinic, School of Rehabilitation, Shahid Beheshti University, and enrolled after informed consent. Allocation to three groups will use block randomization with sealed-envelope concealment. Twelve sessions (3x/week) will be held at Day Hospital and the Zafar Street yoga center. Pre- and post-intervention assessments will occur in sessions separate from treatment, using coded forms. Full participant blinding is not feasible given the observable nature of the interventions.

Participants/Inclusion and exclusion criteria
Women aged 25 to 65 years with urgency urinary incontinence for 6 months to 1 year, confirmed by a specialist physician and a symptom questionnaire, with no regular pelvic floor exercise or yoga in the preceding 6 months; exclusions: pregnancy, pure or predominant stress incontinence, pelvic organ prolapse grade 2 or higher, absent pelvic floor muscle contraction, cognitive impairment, cardiac pacemaker or electrical implant, inability to attend sessions regularly, recent urinary tract infection or pelvic, lumbar, or lower limb surgery, and neurological or sensory disorders of the lower limbs

Intervention groups
Yoga therapy, TTNS, combined yoga therapy and TTN

Main outcome variables
Urgency urinary incontinence symptoms, pelvic floor muscle function, stress, anxiety, depression, quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260907070961N1**
Registration date: **2026-10-23, 1405/08/01**
Registration timing: **registered_while_recruiting**

Last update: **2026-10-23, 1405/08/01**
Update count: **0**

Registration date
2026-10-23, 1405/08/01

Registrant information

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Zohreh Rostam Dokht Effati

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-10-12, 1405/07/20

Expected recruitment end date
2026-11-20, 1405/08/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effects of Yoga and Transcutaneous Tibial Nerve Stimulation on Stress, Anxiety, and Depression Levels, Quality of Life, Pelvic Floor Muscle Function, and Urinary Incontinence Symptoms in Women with Urgency Urinary Incontinence

Public title
Comparison of the Effects of Yoga and Transcutaneous Tibial Nerve Stimulation in the Treatment of Women with Urgency Urinary Incontinence
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age range of 25 to 65 years History of urgency urinary incontinence for the past 6 months to 1 year, based on diagnosis by a specialist physician and confirmed with the Urinary Incontinence Symptom Questionnaire No history of regular pelvic floor exercises, pelvic floor physiotherapy, or yoga/yoga therapy during the past 6 months
Exclusion criteria:
Pregnancy or intention to become pregnant during the study period Presence of pure stress urinary incontinence (without an urgency component) or predominance of the stress component in mixed incontinence Presence of pelvic organ prolapse of grade 2 or higher based on the POP-Q system A score of zero on pelvic floor muscle contraction strength assessment (inability to perform even a minimally detectable contraction) Cognitive impairments preventing proper understanding and execution of exercise instructions (yoga) or cooperation during TTNS sessions Presence of a cardiac pacemaker or other electrical implants (due to potential interference with the TTNS electrical stimulation device) Inability or unwillingness to attend yoga/TTNS sessions regularly according to the study schedule history of urinary tract infection in the past three months History of surgery in the pelvic, lumbar, or lower-limb region in the past year history of neurological disorders such as multiple sclerosis, stroke, Parkinson’s disease, or diabetic neuropathy, based on patient report history of sensory disorders in the lower limbs such as brain injuries, spinal cord injuries, peripheral nerve injuries, or nerve root involvement
Age
From **25 years** old to **65 years** old
Gender
Female

Phase
N/A
Groups that have been masked
- Outcome assessor

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization sequence was generated by an individual independent of the research team, using the online tool randomization.com, applying block randomization with a block size of 6 and an equal 1:1:1 allocation ratio across the three groups (Yoga therapy, TTNS, Combined). The generated sequence was placed into opaque, sealed, and sequentially numbered envelopes, which were held by a person other than the principal investigator. After baseline assessments confirmed a participant's eligibility, the researcher contacted the envelope custodian, and the next envelope in sequence was opened to reveal the assigned group. In this way, the researcher remained unaware of a participant's group assignment until the moment of definitive enrollment.
Blinding (investigator's opinion)
Single blinded
Blinding description
To minimize assessment bias, pre- and post-intervention measurements were conducted in a separate session from the treatment sessions, with assessment forms coded rather than labeled by group assignment. Participants were also asked to refrain from disclosing their intervention group during assessment
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
deputy of research and technology, shahid beheshti university of medical sciences
Street address
Building No. 2 (University Headquarters), 6th Floor, Arabi Street, Yemen Street, Shahid Chamran Highway, Shahid Beheshti University of Medical Sciences and Health Services,
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Postal code
1616913111
Approval date
2026-08-29, 1405/06/07
Ethics committee reference number

IR.SBMU.RETECH.REC.1405.346

Health conditions studied

1

Description of health condition studied
urgency urinary incontinence
ICD-10 code
N39.41
ICD-10 code description
بی‌اختیاری فوریتی ادراری (Urge incontinence)

Primary outcomes

1

Description
Urinary incontinence symptoms (primary outcome)
Timepoint
Before and after 12 intervention sessions
Method of measurement
ICIQ-UI SF questionnaire

2

Description
quality of life (secondary outcome)
Timepoint
Before and after 12 intervention sessions
Method of measurement
I-QOL Questionnaire

3

Description
Level of stress, anxiety, and depression (secondary outcome)
Timepoint
Before and after 12 intervention sessions
Method of measurement
DASS-21 Questionnaire

4

Description
Pelvic floor muscle contraction strength (secondary outcome)
Timepoint
Before and after 12 intervention sessions
Method of measurement
Manual examination using the Modified Oxford scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group 1:Personalized yoga protocol delivered by a yoga instructor with a physiotherapist present, comprising 5 poses: bridge, warrior, garland (malasana), seated forward bend, and leg raises; aimed at strengthening pelvic floor and lower-limb muscles, and teaching proper breathing and relaxation. Each session lasted 1 hour, 3 times/week, for 12 sessions total, in 25 participants.
Category
Treatment - Other

2

Description
Intervention Group 2: Transcutaneous tibial nerve stimulation using an SDZ III stimulator (manufactured 2016) with Nahal adhesive electrodes. The first electrode was placed 3 cm above the medial malleolus and 2 cm posterior on the calf; the second electrode over the calcaneus. Device parameters: 20 Hz frequency, 200 µs pulse duration. Each session lasted 30 minutes, 3 times/week, for 12 sessions total, in 20 participants.
Category
Treatment - Other

3

Description
Intervention group 3: Intervention Group 3: Participants received both interventions concurrently — yoga therapy (1 hour) and transcutaneous tibial nerve stimulation (30 minutes), using the same protocols/equipment described above, 3 times/week, for 12 sessions total, in 20 participants.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Physiotherapy Clinic, School of Rehabilitation, Shahid Beheshti University of Medical Sciences
Full name of responsible person
dr hoda niknam
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School of Rehabilitation Sciences, Shahid Beheshti University of Medical Sciences, Damavand Street (before Bakhshi Fard)
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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
Shahid Beheshti University of Medical 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
Shahid Beheshti University of Medical Sciences
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Position
Physiotherapist
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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
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
Title: Raw pre- and post-intervention participant data
Details: ICIQ-UI SF, I-QOL, DASS-21, and pelvic floor muscle strength scores for 60 participants across three groups, de-identified
When the data will become available and for how long
From publication of the final article, for 5 years
To whom data/document is available
Academic researchers, for research purposes only, with a stated proposal describing intended use
Under which criteria data/document could be used
Research and academic purposes only (non-commercial)
Conditions: Submission of a defined research proposal, approval by the corresponding author, and commitment to maintaining participant confidentiality/non-identification
From where data/document is obtainable
Corresponding author (Dr. Hoda Niknam and PT zohreh rostam dokht effati) via email
What processes are involved for a request to access data/document
Email request outlining research purpose and data use plan → review and approval by corresponding author → de-identified data shared with requester
Comments