Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison the effect of pelvic floor muscle exercise and acupressure on urinary incontinence in women with multiple sclerosis

Protocol summary

Study aim
Comparing the effects of pelvic floor muscle exercise and acupressure on urinary incontinence in women with multiple sclerosis, Department of Special Diseases, Ali Ibn Abitaleb Educational and Medical Center, Rafsanjan, 2025

Design
A controlled, triple-blind, purposive sampling clinical trial based on inclusion criteria and then a minimization randomization method, on 96 patients in three groups: Kegel exercise, acupressure, and control.

Settings and conduct
Study location: MS ward of Ali Ibn Abi Taleb Hospital in Rafsanjan; Study population: All women with MS in Rafsanjan; Type of blinding: Triple blind; Method of blinding: Participants' lack of knowledge of the exact impact of interventions on urinary incontinence, Assessor's lack of knowledge of the type of interventions performed by individuals at home when completing the questionnaire, Use of the letters A, B, C to identify groups to the analyst instead of the names of interventions

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 65 years; Having the physical and cognitive ability to learn and perform interventions; Having at least one month since starting or changing medications that affect urinary incontinence. Exclusion criteria: concurrent use of common complementary therapies; pregnancy; acute or recurrent stage of the disease; urinary tract infection; within 6 months after vaginal delivery; history of third- and fourth-degree lacerations during vaginal delivery

Intervention groups
Intervention group 1: Daily pelvic floor muscle exercise in 3 sets of 10 by the individual for 8 weeks. Intervention group 2: Acupressure by applying constant and continuous pressure with the thumb or other fingers of the individual on the K3 point for 30 minutes three days a week for 8 weeks. Control group: Will not receive any intervention other than routine treatments.

Main outcome variables
Urinary incontinence severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250417065362N1**
Registration date: **2025-08-20, 1404/05/29**
Registration timing: **prospective**

Last update: **2025-08-20, 1404/05/29**
Update count: **0**

Registration date
2025-08-20, 1404/05/29

Registrant information

Name
Fatemeh Akbarzadeh Fathabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-01, 1404/06/10

Expected recruitment end date
2025-10-02, 1404/07/10

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of pelvic floor muscle exercise and acupressure on urinary incontinence in women with multiple sclerosis

Public title

Effect of pelvic floor muscle exercise and acupressure on urinary incontinence in women with multiple sclerosis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 65 years Having the physical and cognitive ability to learn and perform interventions At least one month has passed since starting or changing effective medications for urinary incontinence (such as oxybutynin, tolterodine, and solifenacin)

Exclusion criteria:

Simultaneous use of common complementary therapies such as yoga, psychotherapy, Pilates, meditation Pregnancy Being in the acute or recurrent stage of the disease Urinary tract infection Having other chronic and acute physical and mental illnesses according to medical records Being within 6 months after natural childbirth Having a history of third- or fourth-degree lacerations during vaginal delivery

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

After obtaining the necessary permits, the researchers will first select 96 women (32 in each group) from among the total number of women with multiple sclerosis who have a file at the Center for Special Diseases of Ali Ibn Abi Taleb Hospital in Rafsanjan, using a purposive sampling method based on the inclusion criteria. Eligible participants will then be assigned to groups using the minimization randomization method, according to the levels of incontinence severity. The pre-test will be conducted at four levels: mild (score 1–5), moderate (score 6–12), severe (score 13–18), and very severe (score 19–21), across three groups: intervention with Kegel exercises, intervention with acupressure, and a control group. The first participant at each severity level will be assigned to one of the study groups by random drawing through a sealed envelope. The next participant with the same severity of incontinence will be randomly assigned to one of the two remaining groups. The third participant with the same severity will be assigned to the last group. This process will continue until the desired sample size is achieved.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants will not be informed that the interventions are specifically intended to affect urinary incontinence. The evaluator will remain unaware of the intervention assigned to each participant when completing the questionnaires. To ensure blinding of the data analyst, the study groups will be identified by the letters A, B, and C rather than by the intervention names.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Rafsanjan University of Medical Sciences

Street address

Faculty of Nursing and Midwifery, Parastar Street, Jomhori-e-Eslami Boulevard

City

Rafsanjan

Province

Kerman

Postal code

7718796755

Approval date

2025-05-27, 1404/03/06

Ethics committee reference number

IR.RUMS.REC.1404.031

Health conditions studied

1

Description of health condition studied

Multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description
Urinary incontinence severity based on the score obtained from the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form/ICIQ-UI SF

Timepoint
Before, 4 and 8 weeks after the start of the intervention

Method of measurement
International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form/ICIQ-UI SF

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: In addition to their prescribed medications, participants in this group will perform daily pelvic floor muscle exercises for eight weeks. The exercises will be carried out three times per day (9:00 am, 3:00 pm, and 9:00 pm) in three sets, with each set consisting of 10 repetitions. During each repetition, participants will be instructed to contract their pelvic floor muscles for 6 seconds (contraction phase), followed by a 6-second relaxation phase. To facilitate correct identification and contraction of the pelvic floor muscles, participants will be guided to imagine attempting to prevent the passage of intestinal gas by tightening the ring of muscles around the anus, while avoiding contraction of the leg or buttock muscles. The correct contraction should produce a sensation of the vagina and rectum being pulled upward and inward.

Category
Rehabilitation

2

Description
Second intervention group (Acupressure): In addition to their usual treatments, participants in this group will receive acupressure at the K3 point (located midway between the inner ankle and the Achilles tendon). Acupressure will be self-administered constantly and continuously using the thumb or another finger, three times per week (Saturday, Monday, and Wednesday) at 9:00 am, for a total duration of eight weeks. Each session will last 30 minutes (15 minutes per leg), consisting of 1–2 minutes of constant pressure followed by a 10–15 second rest, repeated throughout the session. To support adherence and ensure regular practice on the specified days, participants will be provided with a timetable to record each completed session. Prior to the start of the intervention and throughout the study, participants will receive detailed guidance from the researcher on the correct method and underlying mechanism of the intervention. This training will be delivered through in-person sessions at the MS department, as well as via telephone, and by sending instructional photos or videos through the EITA software.

Category
Rehabilitation

3

Description
Control group: Will not receive any intervention other than routine treatments.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Ali Ebn Abitalib hospital

Full name of responsible person
Fatemeh Akbarzade Fathabadi

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Hazrat Ali Ibn Abi Talib Educational and Medical Center, Ali Ibn Abi Talib Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Rafsanjan 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
Rafsanjan University of Medical Sciences
Full name of responsible person
Fatemeh Akbarzadeh Fathabadi
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available