

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Investigating Effect of acupressure on urinary control of older women with urinary incontinence

Protocol summary

Study aim

Determining the severity of urinary incontinence in elderly women before and after intervention in both control and intervention groups

Design

Clinical trial with control group, without blinding, randomized on 80 patients. Randomization was performed using quadruple block method.

Settings and conduct

The intervention will be implemented on elderly women in Qazvin day care centers for 12 sessions. Each point will be compressed for one minute until it is satisfactory for the elderly.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Seniors over 60 years old Desire to participate in this research The ability to communicate and have a good mental state based on the ATM questionnaire (score higher than 7) Elderly people with urinary incontinence (urgency, stress) based on the QUID questionnaire (score above 16) Illness period of at least 3 months Exclusion criteria: Failure to participate in the intervention group for more than one week Taking diuretic drugs or other drugs that reduce the symptoms of urinary incontinence during the intervention. Involvement with chronic diseases (urinary tract infection, urinary tract tumor and urinary stones) during the study receiving similar medicine to control urinary incontinence for 1 month

Intervention groups

In this study, ten effective pressure points on urinary incontinence were selected according to the opinion of an acupuncturist and acupressure was performed for the intervention group. During this period, the control group did not receive any intervention or medication to control their urinary incontinence.

Main outcome variables

Urinary Control

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231115060070N1**

Registration date: **2024-01-23, 1402/11/03**

Registration timing: **prospective**

Last update: **2024-01-23, 1402/11/03**

Update count: **0**

Registration date

2024-01-23, 1402/11/03

Registrant information

Name

Sana Motalebifar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 914 985 5606

Email address

sana.motalebifar78@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-03, 1402/11/14

Expected recruitment end date

2024-05-09, 1403/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating Effect of acupressure on urinary control of older women with urinary incontinence	
Public title	Investigating Effect of acupressure on urinary control of older women
Purpose	Supportive
Inclusion/Exclusion criteria	Inclusion criteria: Seniors over 60 years old Desire to participate in this research The ability to communicate and have a good mental state based on the ATM questionnaire (score higher than 7) Elderly people with urinary incontinence (urgency, stress) based on the QUID questionnaire (score above 16) Illness period of at least 3 months Exclusion criteria: Not to participate in the intervention for more than one week Taking diuretic drugs or other drugs that reduce the symptoms of urinary incontinence during the intervention Involvement with chronic diseases (urinary tract infection, urinary tract tumor and urinary stones) during the study receiving similar medicine to control urinary incontinence for 1 month
Age	From 60 years old
Gender	Female
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 80
Randomization (investigator's opinion)	Randomized
Randomization description	a statistician who is blind to the samples will be used to randomly assign the samples. Randomization of the samples will be done with the quadruple block method; In this method, there are six different modes (bbaa'aabb'baba'abab'baab'abba) which will reach the desired sample size by selecting 20 possible blocks. In this method, it is assumed that the people in the intervention group are a and the people in the control group are b.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Factorial
Other design features	For the first time, this study will measure the effect of acupressure on urinary control of elderly women in Iran. Acupressure is a cheap and accessible intervention that can be implemented by the elderly and promotes self-care behavior in the elderly. In addition, this method is a non-invasive intervention that will improve the quality of life of the elderly by controlling their urine. gave

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qazvin University of Medical Sciences

Street address

University building, Shahid Bahonar Blvd.

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Approval date

2023-12-11, 1402/09/20

Ethics committee reference number

IR.QUMS.REC.1402.263

Health conditions studied

1

Description of health condition studied

Urinary incontinence in elderly

ICD-10 code

XIV

ICD-10 code description

Diseases of the genitourinary system

Primary outcomes

1

Description

Urinary control

Timepoint

Urinary control will be measured at the beginning of the study (before the start of the intervention) and 12 sessions after the implementation of the intervention in the elderly.

Method of measurement

Investigating the effect of acupressure on urinary control of elderly women with urinary incontinence, which is measured using the PRAFAB questionnaire.

Secondary outcomes

1

Description

Determining the impact of acupressure on daily life activities

Timepoint

The level of daily life activity will be measured at the beginning of the study (before the start of the

intervention) and 12 sessions after the implementation of the intervention in the elderly.

Method of measurement

PRAFAB questionnaire

2

Description

Determining the effect of acupressure on self-image

Timepoint

The measurement of self-image will be measured at the beginning of the study (before the intervention) and 12 sessions after the implementation of the intervention in the elderly.

Method of measurement

PRAFAB questionnaire

Intervention groups

1

Description

Intervention group: Intervention group: To perform acupressure for the intervention group, the research team determines ten effective points in controlling the symptoms of urinary incontinence according to the opinion of an acupuncturist and also based on previous studies. Before the implementation of the intervention, the researcher discussed the intervention with the participants. she will talk about what will be done for them and give the necessary training regarding the use of drugs, especially the restriction of the use of alpha blocker drugs and sympathomimetics; In addition, the skin condition of the areas under pressure will be checked by the researcher for each elderly person in terms of fragility, and the elderly person will be asked to empty his bladder before the intervention. To start the intervention, the patient is asked to take 5 deep and correct breaths (inhalation through the nose and long exhalation through the mouth); Then the points (Liv2, Ki6, SP6, SP9, ST36) are stimulated bilaterally and the abdominal points (CR3, CR6) are pressed by the researcher alone. Next, the patient lies on his back and the remaining points (BL28, B 23, DU20) are stimulated. According to the patient's age and physical strength, the desired points will be compressed with a slow and regular rhythm and with a pressure that will feel a brief pain, which indicates the flow of qi in the body. According to the patient's appropriate state of mind and the ability to communicate (according to the AMT questionnaire), the patient was talked to during the intervention in order to maintain his peace during the intervention by announcing the satisfactory level of pressure applied to the points. In this intervention, each point will be massaged for one minute in a circular manner and will be performed for 4 weeks and 3 sessions every week with an interval of one day for the elderly, the intervention before noon will take approximately 20 minutes for each participant. Each participant will experience 12 beneficial sessions upon completion of the study.

Category

Rehabilitation

2

Description

Control group: The control group will not receive any complementary medicine and will be present in the test during these four weeks according to their life routine.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Day care centers for the elderly

Full name of responsible person

Sana Motalebifar

Street address

No. 1, Golestan Alley 5, Ayatollah Khamenei Boulevard, Valiasr Crossroads, Qazvin

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Mehdi Mirhashmi

Street address

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Qazvin 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**

Qazvin University of Medical Sciences

Full name of responsible person

Sana Motalebifar

Position

Master of nursing student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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

Qazvin University of Medical Sciences

Full name of responsible person

Sana Motalebifar

Position

Master of nursing student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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

Qazvin University of Medical Sciences

Full name of responsible person

Sana Motalebifar

Position

master of nursing student

Latest degree

Bachelor

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/documentAll data is potentially shareable after de-identifying
individuals**When the data will become available and for how long**The access starts 6 months after the results are
published**To whom data/document is available**In addition to researchers working in academic and
scientific institutions, the data will be available to people
working in industry**Under which criteria data/document could be used**

There are no special conditions

From where data/document is obtainable

Email address: sana.motalebifar78@gmail.com
What processes are involved for a request to access data/document

If you need the data, send a message to the given email address and the data will be sent to you within 48 hours
Comments