

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### **City**

Qazvin

##### **Province**

Qazvin

##### **Postal code**

3415933678

##### **Phone**

+98 914 985 5606

##### **Email**

sana.motalebifar78@gmail.com

## **Sponsors / Funding sources**

## **1**

#### **Sponsor**

##### **Name of organization / entity**

Qazvin University of Medical Sciences

##### **Full name of responsible person**

Mehdi Mirhashmi

##### **Street address**

University building, Shahid Bahonar Blvd.

##### **City**

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##### **Phone**

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##### **Email**

mirhashamismm@gmail.com

#### **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

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**Latest degree**

Bachelor

**Other areas of specialty/work**

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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**

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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**

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**All 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**