Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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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
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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
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