Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

The effect of self-care education on self-efficacy and happiness of elderly women with urinary incontinence, referring to Jahandidegan association in Shiraz, 2018

Protocol summary

Study aim

Determining the effect of self-care education on self-efficacy and happiness in elderly women with urinary incotinence, referring to Jahandidehgan's center of Shiraz, 2018

Design

A clinical trial with a control group, with a parallel group,not blind, simple random assignment, a total of 64 qualified candidates entered the study, in which the target population, elderly women, aged 60 years and older, between November2018 and March 2019

Settings and conduct

The site of the study is the Jahandidehgan center located in Kholdebarin Park, Shiraz. The self-care curriculum consists of 5 sessions. Educational classes for 60 minutes or more within 2 days of the week, the researcher goes to the selected people. The QUID questionnaire is filled in to identify inconsistencies, and they will be included in the study if the minimum score is reached. Then written informed consent and demographic information form, pelvic floor muscle self-efficacy questionnaire related to urinary incontinence, chronic self-efficacy questionnaire of chronic diseases SES6G and Oxford Happiness Questionnaire will be completed by the research samples.

Participants/Inclusion and exclusion criteria

Older women 60 years or more 2. Having urinary incontinence (stress, urgency, or both) for at least 6 months 3. Earn the minimum score of 4 and 6 respectively for stress incontinence and urgency 4. Ability to participate in sports programs related to urinary incontinence 5. Lack of multiple sclerosis 6. Failure to have diabetes

Intervention groups

Self-care education about controlling urinary incontinence, training on pelvic floor muscles, nourishment and drinks, the impact of disease management on happiness and self-efficacy, and increasing self-esteem among the elderly. The pamphlets and instruction leaflets are given to the control group.

Main outcome variables

Self-efficacy; happiness;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121208011691N6**
Registration date: **2018-11-14, 1397/08/23**
Registration timing: **prospective**

Last update: **2018-11-14, 1397/08/23**
Update count: **0**

Registration date

2018-11-14, 1397/08/23

Registrant information

Name

Fariba Ghodsbin Jahromi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 1647 4250

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self-care education on self-efficacy and happiness of elderly women with urinary incontinence, referring to Jahandidegan association in Shiraz, 2018

Public title

The effect of self-care education on self-efficacy and happiness of elderly women with urinary incontinence

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Ability to understand Persian language and communicate Interested in participating in the study Older women 60 years or more Having urinary incontinence (stress, urgency, or both) for at least 6 months Earn the minimum score of 4 and 6 respectively for stress incontinence and urgency Ability to participate in sports programs related to urinary incontinence Being alert (not having cognitive problems like dementia and alzheimer)

Exclusion criteria:

Multiple Sclerosis Diabetes Parkinson's and Thrommers Participate in similar training classes History of urology and congenital urinary tract infections The history of cancer related to genitourinary system

Age

From **60 years** old to **80 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to group the samples according to simple random assignment method, 2 cards (A, B) are assigned to each test and control group. Patients, without knowing each group card, can choose one of their two cards And then enter one of the test or control groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Zand street

City

Shiraz

Province

Fars

Postal code

14336 – 71348

Approval date

2018-10-02, 1397/07/10

Ethics committee reference number

IR.SUMS.REC.1397.665

Health conditions studied

1

Description of health condition studied

Steress urinary incontinence

ICD-10 code

N39.3

ICD-10 code description

Stress incontinence (female)

2

Description of health condition studied

Uregent and mix urinary incontinence

ICD-10 code

N39.4

ICD-10 code description

Other specified urinary incontinence

Primary outcomes

1

Description

Self-efficacy of pelvic floor muscle

Timepoint

Immediately and 2 months later

Method of measurement

Pelvic floor muscle self-efficacy questionnaire

2

Description

Self-efficacy of chronic diseases

Timepoint

Immediately and 2 months later

Method of measurement
Self-efficacy questionnaire for chronic diseases ses6g

3

Description
happiness
Timepoint
Immediately and 2 months later
Method of measurement
Oxford Happiness Inventory

Secondary outcomes

empty

Intervention groups

1

Description
"Intervention group": Self-care education program consists of 5 sessions. Training classes are held for 60 minutes or more, as a participatory learning and lecture in a test group of 2 days a week. In the first session, getting acquainted with the participants, the distribution of the questionnaire, the definition of aging, the incidence of urinary incontinence and its problems are discussed. At the second session, self-care training on pelvic floor muscle and exercises to strengthen the pelvic floor muscle Became In the third session, the self-care education will be expressed on nutrition and drinks and how they are consumed and their effects, how to choose and consume food and drink. In the fourth session, the importance of the impact of disease management on happiness and self-efficacy of individuals is referred, as well as the use of educational materials to manage illness and increase self-esteem and disease control. Finally, the fifth session will summarize the issues and redistribute the questionnaire. In case of absence, a tutorial will be provided to the sample in a training session and the explanations will be given to them individually. If in the group They will have the opportunity to lower their understanding of the subject and level of education from other members of the group by using other teaching aids and placing more time for them, trying to convey and convey the material. Then immediately, two months after the end of training, the self-efficacy and happiness questionnaires will be completed by the samples in the test group.
Category
Behavior

2

Description
"Control group": There is no intervention in this group. Pymflet and educational booklet will be provided to the control group. Then immediately, two months after the end of the training, the intervention group will complete the self-efficacy and happiness questionnaires by the samples in the control group.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
The center of the Jahandidehgan
Full name of responsible person
Rouya Razavi
Street address
Kholdbarin street, The center of the Jahandidehgan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Unes Ghasemi
Street address
Zand street, Central Building of Shiraz University of Medical Sciences
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71348-14336
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Email
www@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Fariba Ghodsbin
Position
PhD / faculty member
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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sadeghi@sums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available