

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of education based on continuous care model on quality of life and self-efficacy in women with urinary incontinence treated by pelvic floor muscle training.

Protocol summary

Study aim

The effect of education based on continuous care model on quality of life and self-efficacy in women with urinary incontinence treated by pelvic floor muscle training.

Design

Randomized trial with control group, don't blinded, with parallel groups and easy sampling.

Settings and conduct

The research environment are: Imam Khomeini Hospital and Arash Hospital affiliated to Tehran University of Medical Sciences. Convenient sampling method will be used. Women who are eligible for the study, will be invited to collaborate and informed consent will be obtained. Data collection tools are consist of three questionnaires: Individual-Midwifery Questionnaire, Urinal Incontinence Quality of Life Questionnaire (IQOL), and Broome self-efficacy questionnaire, will be completed by all participants in the two groups of control and intervention. And four steps of continuous care model will be performed for intervention group for 8 weeks. At the end of the follow-up period, IQOL and Broom questionnaires will be completed by all participants in the two groups of control and intervention and The results of the two groups will be compared and finalized.

Participants/Inclusion and exclusion criteria

Iranian married women with at least 20 years old and don't pregnant, Don't have UTI (Urinary Tract Incontinence), Don't use drugs for treatment of UTI.

Intervention groups

In order to avoid exposing the intervention and control groups, women referred to Imam Khomeini Hospital in the experimental group and women referred to Arash Hospital will be in the control group and the four stages of the follow-up continuous care model will be performed for the test group.

Main outcome variables

1-Quality of life 2-Self-efficacy 3-Urinary incontinence 4-

Conitnuous care model

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160821029446N3**

Registration date: **2018-05-14, 1397/02/24**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-14, 1397/02/24**

Update count: **0**

Registration date

2018-05-14, 1397/02/24

Registrant information

Name

Maryam Damghanian

Name of organization / entity

Nursing and Midwifery Faculty, Tehran University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education based on continuous care model on quality of life and self-efficacy in women with urinary incontinence treated by pelvic floor muscle training.

Public title

The effect of continuous care model on quality of life and self-efficacy in women with urinary incontinence.

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Iranian nationality Married At least 20 years old and older Don't have UTI (urinary tract infection) Don't being pregnant or after pregnancy period Being educated Don't use drugs for treatment of UTI There is no injured urinary tract The diagnosis of UI have been done by a specialist

Exclusion criteria:**Age**From **20 years** old**Gender**

Female

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **68****Randomization (investigator's opinion)**

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

In this study, the intervention group, which includes women with urinary incontinence treated by pelvic floor muscle training in Imam Khomeini Hospital, is trained based on continuous care model . While the control group, which includes women with urinary incontinence treated by pelvic floor muscle training in Arash Hospital, do not receive any more intervention. For them, the questionnaires will be completed at the beginning of the study and 8 weeks later.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Nursing and Midwifery and Rehabilitation Faculty of Tehran University of Medica

Street address

Nursing and Midwifery and Rehabilitation Faculty of Tehran University of Medical Sciences, Tohid Square, Tehran

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2018-01-21, 1396/11/01

Ethics committee reference number

IR.TUMS.FNM.REC.1396.4296

Health conditions studied**1****Description of health condition studied**

Urinary Incontinence

ICD-10 code

N39.41

ICD-10 code description

Urge incontinence

2**Description of health condition studied**

Urinary Incontinence

ICD-10 code

N39.3

ICD-10 code description

Stress incontinence (female)

Primary outcomes**1****Description**

Quality of life

Timepoint

At the beginning of the study, after the end of the intervention

Method of measurement

IQOL quality of life questionnaire

2**Description**

Self-efficacy

Timepoint

At the beginning of the study, after the end of the intervention.

Method of measurement

Broom questionnaire

3

Description

Urinary incontinence

Timepoint

At the beginning of the study, after the end of the intervention.

Method of measurement

Diagnose of the specialist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: With the aim of the effect of education based on continuous care model on quality of life and self-efficacy in women with urinary incontinence treated by pelvic floor muscle training, 3 to 4 education sessions lasting 60 to 40 minutes will be held based on continuous care model with a educational booklet. After that, for eight weeks, the researcher will contact the patients by telephone and SMS for monitoring the treatment process.

Category

Behavior

2

Description

Control group: The control group, which includes women with urinary incontinence treated by pelvic floor muscle training in Arash Hospital, do not receive any more intervention. For them, the questionnaires will be completed at the beginning of the study and 8 weeks later.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeyni Hospital

Full name of responsible person

Maryam Damghanian

Street address

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2

Recruitment center

Name of recruitment center

Arash Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Esmat Karimi

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Number 23, Dameshgh Street, Valiasr Street, Tehran,
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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Faezeh Aliakbari

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Position

Associate Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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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

There is 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