

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

: Comparison the effect of traditional health education with health belief model education on Kegel exercises in middle age women

Protocol summary

Study aim

Comparison the effect of traditional health education with health belief model education on Kegel exercises in middle age women

Design

The training intervention will take place in four sessions in the form of lectures, questions, group discussions, and practical presentation. At the first and second sessions, the educational content axis will be discussed with the participants about the benefits of Kegel exercise and the importance of the risk of urinary incontinence and its complications. Including depression and withdrawal from the community that was presented in the form of lectures, questions and answers. In the third session, the educational content will include a group discussion to overcome perceived barriers (the notion of paying for exorbitant costs for participation in educational classes, and the interruption of everyday life and cultural barriers, such as staying at home in the elderly). To compare barriers with interests and to reach collective decision-making, and in the fourth session to present a practical example of Self-efficacy, by slide, shows the anatomy of pelvic floor muscle that is reinforced during exercises, and how the exercises will be performed, its benefits, and the non-interference of these exercises with daily life. At the end of the fourth session, a training booklet on the sport of Kegel They will be provided with the items taught in these 4 sessions. The purpose of this training booklet is to provide practical guidance, increase perceived sensitivity, perceived severity, perceived benefits and self-efficacy and reduce perceived barriers. Also, a checklist will be given to the recipients for the two months to be recorded. At the end of every two weeks, a call will be made with the clients, and they will talk about the problems with the intervention, and the researchers' contact numbers will be provided to the clients

Settings and conduct

The present study is a randomized controlled trial that

will be performed on 84 middle-aged women in Alvand in 1396. Before the intervention, a researcher-made questionnaire was distributed among all the units under study and the primary performance checklist was completed. Individuals will be randomly divided into two groups of 50. Samples will be selected from sampled patients from the referrals to the clinic after the initial interview and according to the criteria for entering and leaving the study. Then, through a random table, numbers will be grouped into two groups, each with one code (from one to one hundred), and then selecting them one by one, for example, one in the test group and the number two will be in the control group. Finally, 50 people will receive health-based education and 50 routine care and traditional training in health centers. And a meeting Traditional education.

Participants/Inclusion and exclusion criteria

Middle aged women 30 - 45 years old married, have a child or more, have a normal birth history that is more at risk for pelvic prolapse

Intervention groups

In the experimental group, midwifery women aged 30-45 years were trained based on the health belief model. The control group, who will be women between the ages 30-45 years, will benefit from the routine care of comprehensive health centers, and will be provided with a lecture (traditional training) training session and Kegel exercises.

Main outcome variables

Conduct exercise; awareness; perceived sensitivity; perceived severity; perceived benefits; perceived barriers; action guide; self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171205037754N1**

Registration date: **2018-05-01, 1397/02/11**

Registration timing: **retrospective**

Last update: **2018-05-01, 1397/02/11**
 Update count: **0**
Registration date
 2018-05-01, 1397/02/11

Registrant information
Name
 Kobra Hamzehi
Name of organization / entity
Country
 Iran (Islamic Republic of)
Phone
 +98 28 3378 4122
Email address
 k.hamzehi@qums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
 2018-01-30, 1396/11/10
Expected recruitment end date
 2018-02-20, 1396/12/01
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 : Comparison the effect of traditional health education with health beliefs model education on Kegel exercises in middle age women

Public title
 The effect of training in two traditional ways and using an educational model on Kegel exercises

Purpose
 Other

Inclusion/Exclusion criteria
Inclusion criteria:
 Middle aged women 30 - 45 years old married have a child or more have a normal birth history that is more at risk for pelvic prolapse
Exclusion criteria:
 People with proven pelvic prolapse and chronic diseases include high blood pressure, diabetes, cardiovascular, pulmonary, renal psychiatric patients with a history of drug therapy

Age
 From **30 years** old to **45 years** old

Gender
 Female

Phase
 N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **84**
Randomization (investigator's opinion)
 Randomized
Randomization description
 Individuals will be randomly divided into two groups of 50. Samples will be selected from sampled patients from the referrals to the clinic after the initial interview and according to the criteria for entering and leaving the study. Then, through a random table, numbers will be grouped into two groups, each with one code (from one to one hundred), and then selecting them one by one, for example, one in the test group And the number two will be in the control group. Finally, 50 people will receive health-based education and 50 routine care and traditional training in health centers

Blinding (investigator's opinion)
 Double blinded
Blinding description
 The blinded two-way sampling method was used in which the questionnaires were not conducted by an educator who was not included in the type of groups once before the intervention, and then two months after entering the study for both groups, which they also informed about the title The team will not complete and the checklists will be delivered. And data analysis will be performed by the assessor who knows the control and intervention group.

Placebo
 Not used
Assignment
 Other
Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ghazvin University of Medical Sciences
Street address
 Bahrar Blvd.-Qazvin University of Medical Sciences
City
 Ghazvin
Province
 Qazvin
Postal code
 34197-59811
Approval date
 2017-11-03, 1396/08/12
Ethics committee reference number
 IR.QUMS.REC.1396.297

Health conditions studied

1

Description of health condition studied

Pelvic floor muscle weakness

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

perform Cogel exercises

Timepoint

Before and after intervention

Method of measurement

A checklist - a questionnaire

2

Description

Perceived sensitivity

Timepoint

Before and after intervention

Method of measurement

a questionnaire

3

Description

Perceived severity

Timepoint

Before and after intervention

Method of measurement

a questionnaire

4

Description

Perceived benefits

Timepoint

Before and after intervention

Method of measurement

a questionnaire

5

Description

Perceived barriers

Timepoint

Before and after intervention

Method of measurement

a questionnaire

6

Description

Action guide

Timepoint

Before and after intervention

Method of measurement

a questionnaire

7

Description

Efficacy

Timepoint

Before and after intervention

Method of measurement

a questionnaire

8

Description

awareness

Timepoint

Before and after intervention

Method of measurement

a questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A 45-30 year old spouse with a birth history-In the intervention group, an educational program based on the health belief model will be implemented. The training intervention will take place in four sessions in the form of lectures, questions and answers, group discussion and practical presentation. At the end of the fourth session, a training booklet will be provided on Kegel exercise, including the items taught in these 4 sessions. The purpose of this booklet is to provide guidance, increased perceived sensitivity, perceived severity, perceived benefits and self-efficacy, and reduced perceived barriers. Also, a checklist will be given to the recipients for the two months to be recorded. At the end of every two weeks, callers will be contacted and talk about the problems with the intervention.

Category

Prevention

2

Description

Control group: The control group will be selected according to the same criteria as the study group that the test group will then complete and then the questionnaire will be completed by clinical carers. Then they will be given to the control group by the clinical guards of Kegel training in the traditional way and three months later they will be asked to They will be returned to them again by clinical caregivers

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alvand center is a city of Alborz

Full name of responsible person

دکتر مهرعلیان

Street address

-فلکه پست- خیابان عمار

City

الوند

Province

Qazvin

Postal code

36711-34319

Phone

+98 28 3224 4403

Email

k.hamzehi@qums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice-Chancellor for Research in Qazvin University of Medical Sciences

Full name of responsible person

amir pymani

Street address

The Way of the Valley - Al-Shaheed Madani - Text of the No. 1 Research Deputy

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

+98 28 3333 7006

Email

k.hamzehi@qums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice-Chancellor for Research in 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

nezal Aj

Position

Faculty of Nursing and Midwifery

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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nezal_ajh@yahoo.com

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

Qazvin University of Medical Sciences

Full name of responsible person

nezal Aj

Position

Faculty of Nursing and Midwifery

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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

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Full name of responsible person

nezal_ajh@yahoo.com

Position

Faculty of Nursing and Midwifery

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Province

Qazvin

Postal code

36711-34319

Phone

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Email

nezal_ajh@yahoo.com

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

The spss file, the data and statistical analysis through it, as well as the final tables of the conclusions discussed in the chapters of these five theses, will be made available to this site as necessary

When the data will become available and for how long

1/5/97-1/6/97

To whom data/document is available

Medical students

Under which criteria data/document could be used

For use in research project

From where data/document is obtainable

Writer

What processes are involved for a request to access data/document

Via the valid email provided in the previous sections

Comments