

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of application of family- centered empowerment model on the quality of life of women suffering from stress urinary incontinence.

Protocol summary

Summary

The purpose of this semi experimental intervention study is empowering women with stress incontinence in improving quality of life. period of intervention is 1 months, 64 women are randomly divided to the intervention and control groups. The study begins with conducting pretest. The control group do not receive any intervention. The intervention is training sessions based on family-centered empowerment model steps: 1- Increasing the perceived threat (sensitivity and perceived severity of the problem in the test group increase in two 45-minute sessions of group discussion) 2- Problem solving (women become practically familiar with the problem and its solving process during two 45-minute sessions of group discussion) 3- Education Partnership (educational materials in the form of pamphlet is transferred through the women to the active family member) 4- Process evaluation are done with oral questions at the beginning and after the end of each session and final evaluation are conducted with post-test. Inclusion criteria: Having stress incontinence grade 1 and 2 Vaginal prolapse examination and no need for surgical for correction of stress urinary incontinence; Having 60-20 years of age; At least read and write; Family members tend to participate in the intervention; Not pregnant; Not having mental illness such as depression; disability; spinal cord injury and MS; After one year of delivery Exclusion criteria: The presence of irregular and ineffective in educational sessions; Become pregnant during the program; Physical injury during the program. Outcomes include increased quality of life through women's empowerment in improvement of urinary incontinence by reducing complications and related diseases

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013041913064N1**

Registration date: **2013-07-22, 1392/04/31**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-07-22, 1392/04/31

Registrant information

Name

Nadia Kolbadinezhad

Name of organization / entity

Gonabad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Gonabad University of Medical Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2013-08-23, 1392/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of application of family- centered empowerment model on the quality of life of women suffering from

stress urinary incontinence.

Public title

Effect of application of family- centered empowerment model on the quality of life of women suffering from stress urinary incontinence.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Having stress incontinence grade 1 and 2 Vaginal prolapse examination and no need for surgical for correction of stress urinary incontinence; Having 60-20 years of age; At least read and write; Family members tend to participate in the intervention; Not pregnant; Not having mental illness such as depression; disability; spinal cord injury and MS; After one year of delivery Exclusion criteria: The presence of irregular and ineffective in educational sessions; Become pregnant during the program; Physical injury during the program.

Age

From **20 years** old to **60 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

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 Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad, Khorasan Razavi

City

Gonabad

Postal code

9691793718

Approval date

2013-05-28, 1392/03/07

Ethics committee reference number

3/1/92/ک الف

Health conditions studied

1

Description of health condition studied

Stress Urinary Incontinence

ICD-10 code

N39.3

ICD-10 code description

Stress Incontinence

Primary outcomes

1

Description

Quality Of Life

Timepoint

before and 6 weeks after intervention

Method of measurement

IQOL Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Education based on family centered empowerment model steps will be implemented as following: Step one: The first step in family centered empowerment model is, increasing the perceived threat (perceived severity and perceived susceptibility) in the test group. Thus, by holding two group discussions and question and answer of participants in the field of knowledge and awareness associated with stress urinary incontinence and will lead to complications and problems, we will try to improve the perceived threat (severity and perceived susceptibility). The second step in the empowerment model of family-centered, is problem solving: Problem solving will be conducted via group discussions. The goal of this step is, understanding the problem by women and providing its solution. Hence problem-solving sessions, will hold in two 45-minute group discussions in small group of women, with together, under supervision of the researcher, with an objective example of their situation and expressing their experiences and also will discuss in what they have done so far in order to modify their treat of disease and so at this stage, women get practically familiar with their problems and their solving process and this issue will enhance their efficacy. The third step in the family-centered empowerment model, is participation in training: in this step, discussed topics in previous meetings, on educational participation, transferred by the pamphlets to the active member of the family, by women, in order to participate and support of their. The

fourth step in family centered empowerment model is evaluation that includes two stages: process evaluation and final evaluation.

Category

Behavior

2

Description

The control group do not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Gonabad city Health Centers

Full name of responsible person

Nadia Kolbadinezhad

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Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad, Khorasan Razavi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Gonabad University of Medical Sciences

Full name of responsible person

Shahla Khosravan

Street address

Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad, Khorasan Razavi

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Gonabad

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 Gonabad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Nadia Kolbadinezhad

Position

MSc. Student in Commiunity Health Nursing

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty