

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Effect of sexual counseling versus control group on self-concept and sexual satisfaction of women with pelvic organs prolapse: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of sexual counseling versus control group on self-concept and sexual satisfaction of women with pelvic organs prolapse

Design

This is a randomized clinical trial with control group, in which eligible patients will be randomly assigned through the block randomization to the intervention and control groups

Settings and conduct

This study will be performed in the Fatemeh Hospital in Hamadan city on 60 women with pelvic organs prolapse. The patients will be randomly assigned to the intervention and control groups through the block randomization. Blinding is not possible in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 30 to 50 years; Grade II prolapse of the pelvic organs; Having a negative sexual self-concept; Married with a history of at least 2 years of married life; Being literate; Exclusion criteria: Receiving medication and surgical intervention

Intervention groups

Intervention group: Routine treatment in addition to sexual counseling sessions for 45 to 60 minutes once a week for 4 weeks, including familiarity with the anatomy and physiology of the genital tract, pelvic organ prolapse, factors influencing prolapse and effective prevention strategies, sexual cycle in women and men, factors affecting the sexual cycle, helping clients to express their wants and needs, expressing their feelings and any doubts, concerns and questions, emphasis on maintaining a healthy diet and physical activity, providing communication skills techniques, sexual skills, familiarity with methods to increase sexual function, and expressing the importance of positive and negative sexual hypothesis on quality of life. Control group: Just routine treatment

Main outcome variables

Primary outcome: Sexual self-concept, sexual satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N428**

Registration date: **2022-05-21, 1401/02/31**

Registration timing: **prospective**

Last update: **2022-05-21, 1401/02/31**

Update count: **0**

Registration date

2022-05-21, 1401/02/31

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of sexual counseling versus control group on self-concept and sexual satisfaction of women with pelvic organs prolapse: a randomized clinical trial

Public title

Effect of sexual counseling versus control group on self-concept and sexual satisfaction of women with pelvic organs prolapse

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 30 to 50 years; Grade II prolapse of the pelvic organs; Having a negative sexual self-concept; Married with a history of at least 2 years of married life; Being literate;

Exclusion criteria:

Receiving medication and surgical intervention

Age

From **30 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2022-05-07, 1401/02/17

Ethics committee reference number

IR.UMSHA.REC.1401.127

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

Pelvic organs prolapse

ICD-10 code

N81

ICD-10 code description

Female genital prolapse

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

Sexual self-concept

Timepoint

Before the intervention and 2 months later

Method of measurement

Using the Multi-dimensional Sexual Concept-Self Questionnaire

2**Description**

Sexual satisfaction

Timepoint

Before the intervention and 2 months later

Method of measurement

Using the Linda Berg's Sexual Satisfaction Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment in addition to sexual counseling sessions for 45 to 60 minutes once a week for 4 weeks, including familiarity with the anatomy and physiology of the genital tract, pelvic organ prolapse, factors influencing prolapse and effective prevention strategies, sexual cycle in women and men, factors affecting the sexual cycle, helping clients to express their wants and needs, expressing their feelings and any doubts, concerns and questions, emphasis on maintaining a healthy diet and physical activity, providing communication skills techniques, sexual skills, familiarity with methods to increase sexual function, and expressing the importance of positive and negative sexual hypothesis on quality of life.

Category

Treatment - Other

2

Description

Control group: Just routine treatment

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital in Hamadan city

Full name of responsible person

Niloofer Ladoni

Street address

Fatemieh Hospital, Pasdaran Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

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Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

خیابان شهید فهمیده، دانشگاه علوم پزشکی همدان

Position

Student of Midwifery

Latest degree

Master

Other areas of specialty/work

Midwifery

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School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Azita Tiznobaik

Position

PhD in Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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