Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Fatemieh 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
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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
Niloofar Ladoni
Street address
Fatemieh Hospital, Pasdaran Ave.
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
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Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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info.research@umsha.ac.ir
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 پزشکي 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

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Dr. Azita Tiznobaik

Position

PhD in Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data

Contact

Name of organization / entity

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Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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