Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jul 2026

The effect of group counseling based on life skills on sexual intimacy in women of reproductive age

Protocol summary

Study aim
Determining the effect of group counseling based on life skills on sexual intimacy of reproductive age women

Design
A randomized clinical trial with control and intervention groups, with a sample size of 118 people

Settings and conduct
This study will be conducted as a randomized controlled trial on all married women referring to Khalkhal health centers who are willing to participate in the study. At first, the eligible samples were entered into the study with the easy sampling method, and the block method (blocks of four) will be used to randomly assign the samples to two intervention and control groups. Thus, in blocks of 4, two allocations to the intervention group and two allocations to the control group were considered, and there were a total of 6 cases. The blocks of four created will be selected in such a way that the sample size is 118 people.

Participants/Inclusion and exclusion criteria
Entry criteria: age between 18 to 40 years old; getting a score of 60 and below from the sexual intimacy questionnaire (low sexual intimacy). Non-entry criteria: mentioning sexual abuse or harassment before marriage; absence of physical and mental illness the presence of special conditions that prevent normal sexual relations with the spouse; taking neuropsychiatric drugs infertility for any reason; medical prohibition for having children; menopause; previous attendance at sex education classes smoking, tobacco and drugs.

Intervention groups
In the intervention group, counseling will be provided to the test group in the form of 5 groups of 10 people and one group of 9 people. The intervention will be implemented for 8 sessions (two sessions per week) for the test group. There will be no intervention in the control group.

Main outcome variables
Sexual intimacy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201113049377N3**
Registration date: **2023-05-16, 1402/02/26**
Registration timing: **prospective**

Last update: **2023-05-16, 1402/02/26**
Update count: **0**

Registration date
2023-05-16, 1402/02/26

Registrant information

Name
Parvin Mohebbi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 24 3344 6258

Email address
p.mohebbi11@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-21, 1402/02/31

Expected recruitment end date
2023-07-22, 1402/04/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of group counseling based on life skills on sexual intimacy in women of reproductive age

Public title
The effect of counseling on sexual intimacy of reproductive age women
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 40 years old Getting a score of 60 and below from the sexual intimacy questionnaire (low sexual intimacy)
Exclusion criteria:
Mentioning sexual abuse or harassment before marriage Absence of physical and mental illness The presence of special conditions that prevent normal sexual relations with the spouse Taking neuropsychiatric drugs Infertility for any reason Medical prohibition for having children Menopause Previous attendance at sex education classes Smoking, tobacco and drugs
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **118**
Randomization (investigator's opinion)
Randomized
Randomization description
At first, the eligible samples were entered into the study with the easy sampling method, and the block method (blocks of four) will be used to randomly assign the samples to two intervention and control groups. Thus, in blocks of 4, two allocations to the intervention group and two allocations to the control group were considered, and there were a total of 6 cases. Blocks of four created will be selected in such a way that the sample size reaches 118 people. In order to hide the random allocation, the method of sealed opaque envelopes with a random sequence will be used. The tool for generating the sequence will be the table of random numbers.
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 Zanjan University of Medical Sciences
Street address
Ostad Sobooti Blvd.
City
Zanjan
Province
Zanjan
Postal code
4513956184
Approval date
2023-04-25, 1402/02/05
Ethics committee reference number
IR.ZUMS.REC.1402.035

Health conditions studied

1

Description of health condition studied
Women of reproductive age
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Sexual intimacy
Timepoint
Before, immediately and one month after the intervention
Method of measurement
Bagarozzi Sexual Intimacy Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, counseling will be provided to the test group in the form of 5 groups of 10 people and one group of 9 people. The intervention will be implemented for 8 sessions (two sessions per week) for the test group.
Category
Lifestyle

2

Description
Control group: There will be no intervention.
Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Health centers of Khalkhal city
Full name of responsible person
Iraj Etebar
Street address
Mozaffar St
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
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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
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Parvin Mohebbi
Position
Instructor - Faculty member
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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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 further information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
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