

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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)

Phone

+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	<i>No information</i>
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	

<u>1</u>	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	
<u>1</u>	Description of health condition studied Women of reproductive age ICD-10 code ICD-10 code description
Primary outcomes	
<u>1</u>	Description Sexual intimacy Timepoint Before, immediately and one month after the intervention Method of measurement Bagarozzi Sexual Intimacy Questionnaire
Secondary outcomes	empty
Intervention groups	
<u>1</u>	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
<u>2</u>	Description Control group: There will be no intervention. Category

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

City

Ardabil

Province

Ardabil

Postal code

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Email

m.beh@khalums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Hossein Mostafavi

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Azadi Blvd.

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Province

Zanjan

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4513956184

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+98 24 3315 6142

Email

mostafavih@zums.ac.ir

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

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

Midwifery

Street address

Department of Midwifery, School of Nursing and Midwifery, Haj Ahmed Mahdavi Blvd., Shahrak Karmandan

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Roya Salmani

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Student

Latest degree

Bachelor

Other areas of specialty/work

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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