

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 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

*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

## 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**

۵۶۸۱۷۶۱۳۵۱

**Phone**

+98 45 3242 2187

**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

**Street address**

Azadi Blvd.

**City**

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**Phone**

+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**

Parvin Mohebbi

**Position**

Instructor - Faculty member

**Latest degree**

Master

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Roya Salmani

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

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**Email**

roya.salmani72@yahoo.com

**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