

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 2026

### Investigating the Impact of Cognitive Behavioral Counseling on Self efficacy and Sexual attitude in Newly Married Women

#### Protocol summary

##### Study aim

Determining the effect of Cognitive Behavioral Counseling on Self efficacy and Sexual attitudes in Newly married women

##### Design

A counseling intervention study with a control group, with a total of 82 participants who will be divided into two groups of 41 participants. Participants will be divided into two intervention and control groups using random blocks. Randomization codes will be generated using computer randomization software.

##### Settings and conduct

The study will be conducted at the Premarital Counseling Center in Azadshahr, Golestan Province; Couples who previously visited the center and meet the inclusion criteria will be invited to participate. Participants will complete the questionnaires; then the intervention group will receive 8 weekly 90-minute Cognitive Behavioral Counseling sessions. The control group will not receive any intervention. Two and eight weeks after the completion of the counseling sessions, both groups will refill the questionnaires, and the results will be analyzed.

##### Participants/Inclusion and exclusion criteria

Newly married women (1 to 3 Years): A score below the overall average (below 1850) on the Beals Women's Sexual Self efficacy Scale: First marriage and living in a common home: Literate: Do not apply for divorce or separation: Not having a physical or mental disability: Marriage is not compulsory: Neither partner is addicted to drugs: Absence of malignant and incurable diseases

##### Intervention groups

The intervention group will receive 8 90-minute sessions of Cognitive Behavioral Counseling on Self efficacy and Sexual attitudes, once a week. The control group will not receive any intervention. At the end of the study, one counseling session will be held for the control group.

##### Main outcome variables

Sexual self efficacy and sexual attitudes will be measured using the Bills Sexual Self efficacy

Questionnaire and the Hudson Sexual Attitude Questionnaire

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20260225068944N1**

Registration date: **2026-03-01, 1404/12/10**

Registration timing: **prospective**

Last update: **2026-03-01, 1404/12/10**

Update count: **0**

##### Registration date

2026-03-01, 1404/12/10

##### Registrant information

##### Name

Fatemeh Norouzi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 3573 9789

##### Email address

norouzi.f1998@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2026-03-07, 1404/12/16

##### Expected recruitment end date

2026-05-21, 1405/02/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Investigating the Impact of Cognitive Behavioral Counseling on Self efficacy and Sexual attitude in Newly Married Women

**Public title**

Investigating the Effect of Cognitive Behavioral Counseling on Self efficacy and Sexual attitude

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Newly Married Women (1 to 3 Years have Passed Since their Marriage) Have Scored Below the Overall Average (Subscore 1850) on the Beals Women's Sexual Self efficacy Scale First Marriage and Living in a Common home (Permanent Marriage) Be Literate in Reading and Writing Do not Apply for Divorce or Separation Not having a Physical or Mental Disability Marriage Is not Compulsory Neither Partner is Addicted to Drugs Absence of Malignant and Incurable Diseases

**Exclusion criteria:****Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 82

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Participants will be Divided into Two Groups, Intervention and Control, Using Random Blocks A and B (A Intervention Group; B Control Group). Randomization Codes will be Generated Using Computer Randomization Software, and the Size of the Random Blocks will be 4 in 6 Cases With 1:1 Allocation. Opaque and Sealed Envelopes will be Used to Conceal Allocation, and the Envelopes will be Revealed Sequentially When Participants Enter the Study.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Other

**Other design features**

In the Grouping Method, Participants will be Divided into Two Intervention and Control Groups Using Random Blocks A and B (A Intervention Group; B Control Group). In the Intervention Group, 8 90-Minute Sessions of Cognitive Behavioral Counseling on Sexual Self efficacy and Sexual attitudes will be Conducted Once a Week. The Control Group Will not Receive any Intervention.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Arak University of Medical Sciences

**Street address**

Arak County, Arak University of Medical Sciences, Payambar Azam (PBUH) University Complex, Deputy of Research and Technology

**City**

Arak

**Province**

Markazi

**Postal code**

3848176341

**Approval date**

2025-10-19, 1404/07/27

**Ethics committee reference number**

IR.ARAKMU.REC.1404.276

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

Investigating the impact of cognitive behavioral counseling on self efficacy and sexual attitude in newly married women

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Sexual self efficacy, The score of which is determined based on the Women's Sexual Self efficacy Questionnaire developed by Bills and colleagues.

**Timepoint**

At the beginning of the study (before the intervention starts), and 2 and 8 weeks after the end of the counseling sessions

**Method of measurement**

The Women's Sexual Self efficacy Questionnaire by Bills and colleagues

**2****Description**

The sexual attitude score, which is determined based on the Sexual Attitude Questionnaire designed by Hudson and colleagues.

**Timepoint**

At the beginning of the study (before the intervention

starts), and 2 and 8 weeks after the end of the counseling sessions

#### Method of measurement

The Sexual Attitude Questionnaire by Hudson and colleagues

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group: The intervention group will receive 8 90-minute sessions of Cognitive Behavioral Counseling on Sexual self efficacy and Sexual attitudes, one session per week based on the book Cognitive Behavioral Therapy: Basics and Beyond by Judith S. Beck, and obtaining relevant valid certificates by a master's student in midwifery counseling under the supervision of a consultant professor.

##### Category

N/A

#### 2

##### Description

Control group: The control group will not receive any intervention, and at the end of the study, a counseling session will be held for the control group to comply with ethical principles.

##### Category

N/A

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Community Health Center No. 2 - Marriage Counseling Unit

###### Full name of responsible person

Fatemeh Norouzi

###### Street address

Gorgan Street, Shahid Beheshti Street

###### City

Azadshahr

###### Province

Golestan

###### Postal code

4961679631

###### Phone

+98 17 3577 6057

###### Email

norouzi.f1998@gmail.com

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Arak University of Medical Sciences

###### Full name of responsible person

Vice President of Research and Technology

###### Street address

Arak County, Arak University of Medical Sciences, Payambar Azam (PBUH) University Complex, Deputy of Research and Technology.

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###### Phone

+98 86 3417 3532

###### Email

research@arakmu.ac.ir

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Arak 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

Arak University of Medical Sciences

###### Full name of responsible person

Fatemeh Norouzi

###### Position

Masters student

###### Latest degree

Bachelor

###### Other areas of specialty/work

Midwifery

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Shahrood Street, Raja 24

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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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