# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Evaluation of the Effectiveness of counseling based on the acceptance and commitment on sexual self-esteem pregnant women.

## Protocol summary

**Study aim**
Determining the effectiveness of counseling based on acceptance and commitment on sexual self-confidence of pregnant women

**Design**
The clinical trial has a control and intervention group، with parallel groups، blinding in such a way that the information analyst is unaware of the group of people and the participants are aware of their group، randomized in a block method، allocated to the volume of 4 sequences، on 70 patients and Spss will be used for analysis.

**Settings and conduct**
It will be done in the health centers of Isfahan and the data analyst is unaware of the group of people. In the intervention group، 4 midwifery counseling sessions with the approach of acceptance and commitment in the sexual self confidence of pregnant women are held، and in the control group، routine pregnancy care is provided. Participation in the study will be held.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: age between 18-35، married، Pregnancy 18-28 weeks، Iranian nationality، living in Isfahan city، Having at least reading and writing literacy، Consent to participate in the study. Exclusion criteria: A history of hospitalization in the psychiatric department and suffering from mental disorders، having a mental disability، having a physical disability and disability، having an underlying disease، having sexual dysfunction، having a high-risk pregnancy، having a stressful event in the last 6 months، Having a sexual performance score below 15 in the sexual performance questionnaire.

**Intervention groups**
In the intervention group، 4 midwifery counseling sessions with the approach of acceptance and commitment in the sexual self-confidence of pregnant women are held، and in the control group، routine pregnancy care is provided. Participation in the study will be held.

**Main outcome variables**
Sexual self-confidence level of pregnant women.

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20230909059386N1**
Registration date: **2023-11-16, 1402/08/25**
Registration timing: **prospective**

Last update: **2023-11-16, 1402/08/25**
Update count: **0**

**Registration date**
2023-11-16, 1402/08/25

**Registrant information**
**Name**
Fatemeh Yousefian
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
**Phone**
+98 31 3775 0084
**Email address**
fatemehysf1376@gmail.com

**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2024-01-05, 1402/10/15
**Expected recruitment end date**
2024-03-19, 1402/12/29
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Evaluation of the Effectiveness of counseling based on the acceptance and commitment on sexual self-esteem pregnant women.

**Public title**
Effect of counseling based on the acceptance and commitment on sexual self-esteem pregnant women.

**Purpose**
Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Age between 18-35 Married Pregnancy 18-28 weeks Iranian nationality Living in Isfahan city Having at least reading and writing literacy Consent to participate in the study

**Exclusion criteria:**
A history of hospitalization in the psychiatric department and suffering from mental disorders Having a physical disability and disability Having a mental disability Having an underlying disease Having sexual dysfunction Having a high-risk pregnancy Having a stressful event in the last 6 months Having a sexual performance score below 15 in the sexual performance questionnaire

**Age**
From **18 years** old to **35 years** old

**Gender**
Female

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **70**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Restricted Block randomization. Blocking is usually used in order to balance the number of samples allocated to each of the studied groups. This feature helps the researchers so that the number of samples allocated to each of the studied groups is equal in cases where intermediate analyzes are needed during the sampling process. The size of all the blocks is equal and we will use 4 blocks in this experiment.

**Blinding (investigator's opinion)**
Not blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**
The data analyst is blinded.

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**
Ethics committee of shahrod University of Medical Sciences

**Street address**
Research and Technology Vice Chancellor, Shahrood University of Medical Sciences and Health Services,7 Tir Square

**City**
Shahrood

**Province**
Semnan

**Postal code**
۳۶۱۴۷۷۳۹۴۳

**Approval date**
2023-10-23, 1402/08/01

**Ethics committee reference number**
IR.SHMU.REC.1402.122

## Health conditions studied

**1**

**Description of health condition studied**
Sexual confidence

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

**1**

**Description**
Sexual self-confidence level of pregnant women

**Timepoint**
Before the intervention; in the last intervention session; one month after the last session

**Method of measurement**
The questionnaire of this study is the Women's Sexual Self-Esteem Questionnaire-Short Form (SSEI-W-SF).

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
In the intervention group, we will have 4 sessions of 90 minutes in 4 weeks with a counseling approach based on acceptance and commitment.

**Category**
Lifestyle

**2**

**Description**
Control group: routine prenatal care
**Category**
N/A

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Farhangian health center
**Full name of responsible person**
Dr shamsolsadat izadi
**Street address**
Bagh ziyar street
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174744383
**Phone**
+98 31 3776 9646
**Email**
Dr_shamsolsadat_izadi@gmail.com

**2**

**Recruitment center**
**Name of recruitment center**
Shahid fadayi health center
**Full name of responsible person**
Dr farshad amiri
**Street address**
Hakim nezami three way
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174744383
**Phone**
+98 31 3628 9009
**Email**
Farshad_amiri@yahoo.com

**3**

**Recruitment center**
**Name of recruitment center**
Sodan health center
**Full name of responsible person**
Dr samane landaran
**Street address**
Samadiye street
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174744383
**Phone**
+98 31 3738 9999
**Email**
Landaran_samane@gmail.com

**4**

**Recruitment center**
**Name of recruitment center**
Dastgerd health center
**Full name of responsible person**
Dr behzad laghavi
**Street address**
Ghaemiye Street
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174744383
**Phone**
+98 31 3780 8575
**Email**
Laghavi.behzad@yahoo.com

**5**

**Recruitment center**
**Name of recruitment center**
Maleksgahr health center
**Full name of responsible person**
Dr baghei
**Street address**
Malekshahr Street
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174744383
**Phone**
+98 31 3626 1484
**Email**
Dr_bagheri@gmail.com

**6**

**Recruitment center**
**Name of recruitment center**
Gole yas health center
**Full name of responsible person**
Dr samane landari
**Street address**
Atishgah street
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174744383
**Phone**
+98 31 3771 8170

**Email**
Landari_samabe@gmail.com

**7**

**Recruitment center**
**Name of recruitment center**
Amirhamze health center
**Full name of responsible person**
Dr fateme moradpor
**Street address**
Koye amiriye street
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174744383
**Phone**
+98 31 3668 7303
**Email**
Moradpor246_fateme@gmail.com

**8**

**Recruitment center**
**Name of recruitment center**
Vahid health center
**Full name of responsible person**
Dr shahnaz fesharaki
**Street address**
Vahid street
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174744383
**Phone**
+98 31 3228 1121
**Email**
Fesharaki_shahnaz12@gmail.com

**9**

**Recruitment center**
**Name of recruitment center**
Sepahanshahr health center
**Full name of responsible person**
Dr faramarz emamdost
**Street address**
Ghadir Street
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174744383
**Phone**
+98 31 3669 8066
**Email**
Dr_emamdost@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shahroud University of Medical Sciences
**Full name of responsible person**
Dr mohamadhasan emamian
**Street address**
7 tir Square
**City**
Shahrood
**Province**
Semnan
**Postal code**
۳۶۱۴۷۷۳۹۴۳
**Phone**
+98 23 3239 5054
**Email**
emamian@shmu.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Shahroud 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**
Shahroud University of Medical Sciences
**Full name of responsible person**
Fatemeh yousefian
**Position**
Student
**Latest degree**
Bachelor
**Other areas of specialty/work**
Midwifery
**Street address**
Jahangiri dead end، simin's three ways
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174744383
**Phone**

+98 31 3775 0084

**Email**

Fatemehysf1376@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Fatemeh yousefian

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

Jahangiri dead end، simin's three ways.

**City**

Isfahan

**Province**

Isfehan

**Postal code**

8174744383

**Phone**

+98 31 3775 0084

**Email**

Fatemehysf1376@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Fatemeh yousefian

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

Jahangiri dead end، simin's three ways.

**City**

Isfahan

**Province**

Isfehan

**Postal code**

8174744383

**Phone**

+98 31 3775 0084

**Email**

Fatemehysf1376@gmail.com

## 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