

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 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)

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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

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Shahrood

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Postal code

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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

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Recruitment center

Name of recruitment center

Shahid fadaye health center

Full name of responsible person

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Recruitment center

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Recruitment center

Name of recruitment center

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Full name of responsible person

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Recruitment center

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7**Recruitment center****Name of recruitment center**

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8**Recruitment center****Name of recruitment center**

Vahid health center

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9**Recruitment center****Name of recruitment center**

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Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahroud 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

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

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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

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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

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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