

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Determination of effect of Counseling based on Sexual Health Model on sexual function and Dysfunctional sexual beliefs in Primigravida women

Protocol summary

Study aim

Determining the effect of counseling based on Sexual Health Model on sexual function and sexual dysfunctional beliefs in Primigravida women

Design

A clinical trial with Simple randomization, parallel groups, without blinding and it is conducted on 56 eligible primigravida women.

Settings and conduct

56 eligible primigravid women who referred to 4 health centers in Meibod city were selected according to the Inclusion and Exclusion criteria, then randomization software was used to divide them into two intervention(28 people) and control groups(28 people). After obtaining informed consent, sexual function questionnaire and sexual dysfunctional beliefs questionnaire are completed by them, and then intervention group will receive routine care of health center and 4 group counseling sessions (90 minutes) weekly based on sexual health model, control group will receive routine care of health center and educational Content. then questionnaires will be completed again 2 and 4 weeks after counseling sessions and the results will be statistically analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Iranian, Ability to read and write, The first pregnancy (14 - 28 weeks), Age range (15- 49 years), Single pregnancy, Based on the sexual dysfunctional beliefs questionnaire; Have at least one dysfunctional belief. Exclusion criteria: High-risk pregnancy, Having severe depression, Prohibition of Vaginal intercourse, Drug or alcohol addiction, Happening stressful events during the past 6 months .

Intervention groups

Intervention group will receive routine care of health center and 4 group counseling sessions (90 minutes) weekly based on sexual health model, control group will receive routine care of health center and educational Content.

Main outcome variables

sexual function and sexual dysfunctional beliefs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230618058510N1**

Registration date: **2023-09-27, 1402/07/05**

Registration timing: **prospective**

Last update: **2023-09-27, 1402/07/05**

Update count: **0**

Registration date

2023-09-27, 1402/07/05

Registrant information

Name

Marzieh Zare

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3234 4618

Email address

m.zare@stu.ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-20, 1402/07/28

Expected recruitment end date

2024-03-18, 1402/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination of effect of Counseling based on Sexual Health Model on sexual function and Dysfunctional sexual beliefs in Primigravida women

Public title

Determination of effect of Counseling based on Sexual Health Model on sexual function and Dysfunctional sexual beliefs in Primigravida women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Willing to participate in the study Iranian and resident of Meibod city Ability to read and write in Persian The first pregnancy with a gestational age of 14 to 28 weeks Age range from 15 to 49 years Single pregnancy Having official marriage Based on the sexual dysfunctional beliefs questionnaire; Have at least one dysfunctional belief

Exclusion criteria:

Having a high-risk pregnancy Studying books or consulting about marital relations during the past 6 months Suffering from known diseases Being under psychiatric treatment for mental disorders and having severe depression Prohibition of sex Drug or alcohol addiction in any of couple Happening stressful events during the past 6 months for any of couples Taking medicine affecting sexual function for any of couples

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization of this study is simple randomization. Among the primigravida women referred to clinics of Meibod city, 56 people are eligible to enter the inclusion criteria and sequence of random numbers with random allocation software, these women are divided into two groups(28people in intervention group and 28people in control group)

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Clinical Practice With Control Group

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Sadoughi University of Medical Sciences

Street address

Shahid Sadoughi University of Medical Sciences, Shahid Bahonar Bld, Yazd

City

Yazd

Province

Yazd

Postal code

8916189165

Approval date

2023-08-21, 1402/05/30

Ethics committee reference number

IR.SSU.REC.1402.051

Health conditions studied

1

Description of health condition studied

sexual function and sexual dysfunction beliefs

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The score of sexual dysfunction beliefs

Timepoint

Measurement of sexual dysfunction beliefs score before, 2and 4 weeks after the completion of counseling

Method of measurement

Sexual dysfunction beliefs questionnaire

2

Description

The score of sexual function

Timepoint

Measurement of sexual function score before, 2and 4 weeks after the completion of counseling

Method of measurement

Sexual function questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: will receive 4 group counseling sessions (90 minutes) weekly based on sexual health model and routine services by the staff in healthcare centers.

Category

N/A

2

Description

Control group: The active control group will receive routine services by the staff in healthcare centers also receives the educational content (offline)

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers in Meibod city

Full name of responsible person

Mahshid Bokaie

Street address

School of Midwifery Nursing, Bouali Alley, Teymsar Fallahi St, Safaieh, Yazd

City

Meibod

Province

Yazd

Postal code

8916877443

Phone

+98 35 3824 1751

Email

mah_bokaie@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amin Salehi Abargouei

Street address

Central Organization of Shahid Sadoughi University of Medical Sciences, Yazd, Dr. Bahonar Square, Yazd

City

Yazd

Province

Yazd

Postal code

8916978477

Phone

+98 35 3726 3733

Email

abargouei@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Mahshid Bokaie

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

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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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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All individual data of study participants can be shared after de-identification.

When the data will become available and for how long

After results publication.

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions, and people working in industry can apply to receive them

Under which criteria data/document could be used

Scientific usage.

From where data/document is obtainable

mah_bokaie@yahoo.com

What processes are involved for a request to access data/document

One week after receiving the applicant's email.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Mahshid Bokaie

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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