Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 routin care of health center and 4 group counseling sessions (90 minutes) weekly based on sexual health model, control group will receive routin care of health center and educational Content. then questionnaires will be completed again2 and 4 weaks 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 routin care of health center and 4 group counseling sessions (90 minutes) weekly based on sexual health model, control group will receive routin 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:
Welling 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 weaks 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 weaks 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
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Postal code
8916978477
Phone
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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
School of Midwifery Nursing, Bouali Alley, Teymsar Fallahi St, Safaieh, Yazd
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Name of organization / entity
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Full name of responsible person
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Person responsible for updating data

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mah_bokaie@yahoo.com

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