

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of midwifery counseling's effectiveness on amendment of dysfunctional sexual beliefs of pregnant, and improvement of sexual life's quality and sexual competence in pregnant women through cognitive-behavioral aspects.

Protocol summary

Study aim

Evaluation of midwifery counseling's effectiveness on amendment of dysfunctional sexual beliefs, and improvement of sexual life quality and sexual competence in pregnant women through cognitive-behavioral aspects.

Design

This case-control trial study was conducted with method of parallel group randomization on 45 pregnant women.

Settings and conduct

A total of 94 pregnant women who met the inclusion criteria were collected from the health centers of Rey city and then they will be randomly divided into two group of intervention and control. Subsequent to interventions, the level of dysfunctional sexual beliefs, sexual competence, and then quality of sexual life in pregnant women will be collected using a standard questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria: women with gestational age of 15 to 28 weeks, women without serious physical and psychological illness, women with literacy of at least writing and reading, wanted pregnancy, women with moderate to high scores of dysfunctional sexual beliefs, and don't taking medicine (other than pregnancy supplements) Exclusion criteria: participants with pregnancy complications, history of alcohol usage and smoking, and use of medications affecting sexual desire including anti-depressants and anti-hypertensive drugs.

Intervention groups

Intervention group: patients who completed a questionnaire and attended in 4-session long program of cognitive-behavioral counseling (a 90-minute session weekly) Control group: women who completed a questionnaire and received routine pregnancy care.

Main outcome variables

Dysfunctional sexual beliefs; sexual competence; quality of sexual life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210221050439N1**

Registration date: **2021-07-11, 1400/04/20**

Registration timing: **retrospective**

Last update: **2021-07-11, 1400/04/20**

Update count: **0**

Registration date

2021-07-11, 1400/04/20

Registrant information

Name

Masoumeh Rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3612 5532

Email address

rezayim3@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-05, 1400/02/15

Expected recruitment end date

2021-07-06, 1400/04/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of midwifery counseling's effectiveness on amendment of dysfunctional sexual beliefs of pregnant, and improvement of sexual life's quality and sexual competence in pregnant women through cognitive-behavioral aspects.

Public title
The effect of dysfunctional sexual beliefs on quality and sexual competence of pregnant women.

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
absence of serious physical and psychological diseases
wanted pregnancy (planned pregnancy) literacy of at least reading and writing having average-to-high score of dysfunctional sexual belief absence of medication use (pregnancy supplements are exempted) gestational age of 15-28 weeks at the time of study
Exclusion criteria:
presence of pregnancy complications such as miscarriage history of cervical cerclage presence of gestational hypertension presence of placenta previa, the possibility of preterm delivery in the current pregnancy history of alcohol consumption and smoking consumption of medications influencing sexual desire including antidepressants and antihypertensive drugs

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **94**

Randomization (investigator's opinion)
Randomized

Randomization description
We used quadruple block method and these blocks were randomly designed in Excel software then Equivalent groups were assigned: A to the intervention group and B to the control group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahroud University of Medical Sciences

Street address

Shahroud University of Medical Sciences, 7th of Tir Square

City

Shahroud

Province

Semnan

Postal code

36147-73947

Approval date

2021-04-11, 1400/01/22

Ethics committee reference number

IR.SHMU.REC.1400.009

Health conditions studied

1

Description of health condition studied

Correction of dysfunctional sexual beliefs of pregnant women

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Improving the quality of sexual life and sexual function of pregnant women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Dysfunctional sexual beliefs in pregnancy

Timepoint

Before and after the intervention and 4 weeks after the intervention

Method of measurement

Questionnaire on dysfunctional sexual beliefs in pregnancy

Secondary outcomes

1

Description

Quality of sexual life
Timepoint
Before and after the intervention and 4 weeks after the intervention
Method of measurement
Simond Women's Quality of Sexual Quality Questionnaire

2

Description
Sexual function
Timepoint
Before and after the intervention and 4 weeks after the intervention
Method of measurement
Rosen Women Sexual Function Questionnaire

Intervention groups

1

Description
Intervention group includes 47 pregnant women who will fill out standard questionnaires regarding dysfunctional sexual beliefs, sexual function and quality of sexual life twice, once before and once after the intervention. The intervention is composed of 4 sessions of cognitive-behavioral counseling for 90 minutes each week. The syllabi of this counseling course are as follow: cognitive triad (1st session), ABC model of cognitive behavioral therapy (2nd session), problem-solving skills (3rd session), and coping strategies for dysfunctional sexual beliefs (4th session).
Category
N/A

2

Description
Control group: No intervention is performed in the control group.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Rey City Health Center
Full name of responsible person
Masomeh Rezaei
Street address
Shahid Ghazizadeh St., Kianshahr
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Mohamad Hasan Emamian
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Shahroud University of Medical Sciences, 7th of Tir Square
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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
Masomeh Rezaei
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The data obtained from this project will eventually be reported generally and personal information of individuals will remain confidential.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

Demographic information and information about the main outcome of this project can be shared.

When the data will become available and for how long

The data become accessible a year after publishing of the results.

To whom data/document is available

The data of this project can be shared by all aspiring and working researchers in academic and scientific institutes.

Under which criteria data/document could be used

After suitable citation, the use of the data is unrestricted to improve the quality of similar studies .

From where data/document is obtainable

The data of the present research can be requested through writing an email to Rezayim3@gmail.com

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

After confirming the eligibility of the person requesting the information, the data will be sent as soon as possible.

Comments