

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

The Effect of Group Sexual Health Counseling Based on Cognitive Behavioral Approach on the Dysfunctional Belief and Sexual Satisfaction of Women Primigravida

Protocol summary

Study aim

Investigation the effect of group counseling on sexual health based on cognitive-behavioral approach on ineffective beliefs and sexual satisfaction primigravida women

Design

Clinical Practice With Control Group

Settings and conduct

After obtaining permission from the Research and Technology Dept. and the Ethics Committee of the University, the women who were first eligible pregnant referred to two health centers in Isfahan, 52 were selected according to the criteria of entry and exit of the study and then randomly assigned to two groups Equal to intervention and control. After getting informed consent, sexual satisfaction and sexual misconduct questionnaires are completed by the subjects, and then eight 90-minute weekly counseling sessions are held immediately after the completion and one month after The completion of the questionnaires was completed again and the results were analyzed statistically Will.

Participants/Inclusion and exclusion criteria

First pregnancy, weeks 6 to 24, having primary education, passing one year of marital life, having a pregnancy, having no medical and mental illness, no drug use, having no sexual dysfunction in yourself and a pregnant wife, a common life of permanent monogamy, Lack of acute mental illness and non-addiction and wife to drug and alcohol , the lack of use of drugs, no problems during the study , abnormal fetal heart patterns Or reduced fetal movements and the absence of medical conditions or drugs that may affect the libido. .

Intervention groups

Intervention and control group 52 Primigravid women 6 to 24 weeks. For intervention group 8 sessions group counseling with a cognitive behavioral approach will be conducted once a week and will not be conducted for

interventional control group.

Main outcome variables

Ineffective sexual beliefs and sexual satisfaction

General information

Reason for update

Acronym

Cognitive-Behavioral Therapy .CBT

IRCT registration information

IRCT registration number: **IRCT20181207041875N1**

Registration date: **2019-05-30, 1398/03/09**

Registration timing: **retrospective**

Last update: **2019-05-30, 1398/03/09**

Update count: **0**

Registration date

2019-05-30, 1398/03/09

Registrant information

Name

Marzieh Zareigashiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3263 0018

Email address

m.zarei@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-01, 1397/09/10

Expected recruitment end date

2019-03-30, 1398/01/10

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Group Sexual Health Counseling Based on Cognitive Behavioral Approach on the Dysfunctional Belief and Sexual Satisfaction of Women Primigravida

Public title
The Effect of Group Sexual Health Counseling Based on Cognitive Behavioral Approach on the Dysfunctional Belief and Sexual Satisfaction of Women Primigravida

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

First pregnancy Gestational age 6 to 24 weeks Reading and writing literacy At least one year of marital life The desire for pregnancy The absence of medical and psychological illness, lack of medication lack of sexual dysfunction in themselves and the spouse before pregnancy The common life of a single monogamous person His lack of addiction and his wife to drugs and alcoholic beverages (according to Fred) lack of mental and psychological illnesses and spouses Non-use of psychosocial drugs (tricyclic antidepressants, inhibition Open serotonin absorption and ...)

Exclusion criteria:

The incidence of any pregnancy problem during the study (Abortion, Decollete, Abnormal Embryo, Cord Prolapse, Blood, Diabetes, Hypertension, Preterm Delivery, etc) Abnormal fetal heart patterns, or reduced fetal movements in a way that requires medical intervention. The advent of medical conditions or medications that may affect sexual function during an intervention Incineration criteria included

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 52

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization of this study is simple randomization. Among the primigravida women referred to clinics of Isfahan, 52 people are eligible to enter the inclusion criteria and will be assigned to each person by using the table of pictures to be divided into two groups of intervention and control.

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 Shahid Sadoughi University of Medical Sciences, Yazd

Street address

End of Yas, Hariri Alley, Motahari Ave.

City

Yazd

Province

Yazd

Postal code

8917698148

Approval date

2018-12-01, 1397/09/10

Ethics committee reference number

IR.SSU.REC.1397.112

Health conditions studied

1

Description of health condition studied

dysfunctional belief and sexual satisfaction

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The score of noneffective beliefs sexual

Timepoint

Measurement of sexual beliefs score before, after and one month after the completion of counseling

Method of measurement

noneffective beliefs questionnaire

2

Description

The score of sexual satisfaction

Timepoint

Measurement of sexual satisfaction score before, after and one month after the completion of counseling

Method of measurement

Sexual satisfaction Questionnaire Larson sexual

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For routine care intervention group and 8 sessions of 90 minutes, group counseling with cognitive behavioral approach is held once a week.

Category

Behavior

2

Description

Control group: Only routine pregnancy is done.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers in Isfahan province

Full name of responsible person

Marzieh Zarei Gashiri

Street address

no.59 , alley shahid mahmmod zarei , Ave sarvestan,
Ave moshtagh dovom

City

Esfahan

Province

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8158168688

Phone

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Email

zareei.marzi1512@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaei

Street address

Faculty of midwifery nursery Bu,Ali Alley, Thimsar
Fallahi Street, Safeie, Yazd

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yazd

Province

Yazd

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8915173160

Phone

+98 35 3824 1751

Email

M.zarei1512@ssu.ac.ir

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

Marzieh Zarei Gashiri

Position

Master,s degree in midwifery counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Faculty of midwifery nursery Bu,Ali Alley, Thimsar
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Email

M.zarei@ssu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr.mahshid bokaie

Position

PhD in reproductive health

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Marzih zarei gashiri

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Zarei.marzi1512@yahoo.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

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Title and more details about the data/document

The results of the clinical study will be published as a paper

When the data will become available and for how long

Immediately after publishing the results

To whom data/document is available

All researchers

Under which criteria data/document could be used

Scientific using with citation to article

From where data/document is obtainable

Email:m.zarei@ssu.ac.ir

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

Up to one week after correspondence by email

Comments