Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Effect of BETTER model Sexual Counseling on sexual Quality of Life and Depression in pregnancy

Protocol summary

Study aim

1.Effect of BETTER model Sexual Counseling Depression in Pregnancy 2.Effect of BETTER model Sexual Counseling on sexual Quality of Life and Depression in Pregnancy

Design

This study was a randomized clinical trial that has an intervention group and a control group.Webber is performed on 64 patients by randomization of random block sequencing website

Settings and conduct

Counselling sessions are carried out in a comprehensive health base of the city. People enter the research community, which is the score of depression under 12, is completed for both groups. The intervention is carried out on two sessions of sexual counseling, 45 minutes, which is determined by the mother of the sessions, the control group will only receive routine care in the intervention group.The outcomes of the study were assessed by questionnaires a month later

Participants/Inclusion and exclusion criteria

tend to participate in research, age range between 18-35 years having minimal literacy of reading and writing of drug or alcohol failure to have chronic and psychological diseases during pregnancy and before pregnancy and having no history of abortion or infant death of pregnancy is not a history of infertility Or pregnancy, with the help of fertility,

Intervention groups

the research community of the intervention in the form of two 45-minute sexual counseling sessions, which is the interval of sessions by mother and within 14th25weeks, based on the BETTER model in the intervention group.The control group will only receive routine care

Main outcome variables

Quality of sexual life is measured by the quality of Sexual Life questionnaire (SQOL-F). SQOL-F is a tools that linking in the form of sexual function and quality of life of women. Depression, this consequence is assessed by Edinburgh questionnaire. The aim of this study was to assess postpartum depression and pregnancy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200516047467N1**
Registration date: **2020-06-11, 1399/03/22**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-11, 1399/03/22**
Update count: **0**

Registration date

2020-06-11, 1399/03/22

Registrant information

Name

Maral Forqani far

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3282 2262

Email address

maralforqanifar@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-04, 1399/03/15

Expected recruitment end date

2021-01-04, 1399/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of BETTER model Sexual Counseling on sexual Quality of Life and Depression in pregnancy

Public title

effect of sexual counseling on the sexual quality of life and depression in pregnancy

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnancy required in the second trimester of pregnancy (15 weeks to 25 weeks Age 18-35 years Have a minimum of literacy Do not use drugs or alcohol Have no chronic mental illness before and during pregnancy No history of miscarriage or infant death Single infant No history of infertility or pregnancy with assisted reproductive techniques(ART) There are no pregnancy problems such as prolactinemia or fetal problems such as weight loss dont have Sexual disease before and now Depression scores below 12 with EPDS

Exclusion criteria:

Have diabetes Take drugs that affect the sexual cycle Marital disputes or abstinence from partner for any reason

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: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization method, which is one of the following limited randomization groups, is used. 4-block method is used to create a random allocation sequence in this study. Pregnant women will be selected according to the criteria of the researcher and are randomly assigned to the central Randomization method in two groups (intervention) and B (control).In order to perform this task, the sequencing website will be created by random blocks.In this study, by using the software, by the methodology consultant, the random allocation sequence is obtained., in this study, the random sequence of blocks will be provided to the specific of the research team, which is responsible for the random allocation.With the arrival of mothers to study and register them at any centre, at the same time, all persons and their conditions will be recorded in a central list, and they will receive a code in order to log in.Then it is responsible for the allocation of codes to receive and assign people to intervention and control groups.Mhaghqbrasas the entry of participants to study with the relevant center and questions about the random allocation of the participant to the study group.Communication methods include using your phone, message, fax, email, etc

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

7 tir str uni shmu

City

Shahroud

Province

Semnan

Postal code

7575135534

Approval date

2020-05-09, 1399/02/20

Ethics committee reference number

IR.SHMU.REC.1399.043

Health conditions studied

1

Description of health condition studied

depression during pregnancy

ICD-10 code

F33.1

ICD-10 code description

Major depressive disorder, recurrent, moderate

Primary outcomes

1

Description

sexual quality of life

Timepoint

Before the intervention, after the intervention, one month after the intervention

Method of measurement

Sexual quality of life questionnaire is a means that the linking of the quality of sexual function, women in the life of females.It is a report that focuses on the confidence of

the relationship between women, emotional and communicative beliefs

2

Description
depression
Timepoint
Before the intervention, after the intervention, one month after the intervention
Method of measurement
Edinburgh Depression Questionnaire is used to measure depression during pregnancy and postpartum period

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the case of two weeks, a 45-minute sex consultation with a one-week interval is performed individually for mothers 14-25 weeks pregnant in the intervention group.Each session is based on this model including 6 steps: 1-bieng-2-explain about whether sexual relationship is part of quality of life-3-tell a bout their concerns in the future-4-time of intervention-5-education-6-Record of interventions
Category
Behavior

2

Description
Control group: recieves routine care
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Bahmaee Helth Center
Full name of responsible person
Maral Forqanifar
Street address
Qods St,Bahmaee Helth Center
City
lilak
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Kohgilouyeh-va-Boyrahmad
Postal code
7575154459
Phone
+98 74 3282 2262
Email
Maria22121372@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Mohammad Hasan Emamian
Street address
Seven Tir St,Shahroud Univesity of Medical Sciences
City
Shahroud
Province
Semnan
Postal code
3614773955
Phone
+98 23 3239 5014
Email
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
Maral Forqani far
Position
Midwife
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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Rahbari st,saadi
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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Midwife

Latest degree

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Title and more details about the data/document

The entire potential data is unidentifiable after being detected by peopl

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Those who are allowed to submit an application for personally identifiable information with other documents

From where data/document is obtainable

Shahroud University of Medical Sciences maral forqani far

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

6months of Waiting

Comments