

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of virtual based cognitive-behavioral sexual counseling on sexual function, satisfaction and intimacy in pregnant women

Protocol summary

The primary variables are sexual function and secondary outcome variables are sexual satisfaction and intimacy

Study aim

Determining the effect of virtual cognitive behavioral sexual counseling on sexual function, satisfaction and intimacy of pregnant women

Design

The study will be performed on 80 pregnant women who are randomly divided into intervention and control groups. Block randomization will be used for randomization using internet tools.

Settings and conduct

Sampling is done in comprehensive health centers and bases in Alborz province. First, a list of all comprehensive health centers and bases in Alborz province is prepared and ten centers that are suitable in terms of the number of pregnancy coverage are selected. preliminary sampling will be available in such a way that the researcher will contact the eligible people using the phone number in the file and giving explanations about the goals. Eligible volunteers are placed on a list with a row number. Block randomization is used for random allocation, so that the online block randomization tool will be used.

Participants/Inclusion and exclusion criteria

Sexual function score less than 28, first pregnancy, age 18 to 35 years, singleton and desire, gestational age 16 to 24 weeks, low risk pregnancy, internet literacy, absence of sexual dysfunction in the spouse, no severe mental illness, no grief in the three months before the study, no attending similar treatment sessions in the last six months

Intervention groups

This study will be performed on 80 pregnant women in comprehensive health centers who are eligible to enter the study. First, participants will be divided into two groups of intervention and control. Then, the members of the intervention group participate in 8 sessions of group sexual counseling virtually, and the control group is placed under the usual care of the health center.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161230031662N10**

Registration date: **2021-06-21, 1400/03/31**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-21, 1400/03/31**

Update count: **0**

Registration date

2021-06-21, 1400/03/31

Registrant information

Name

Razieh Lotfi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3430 4433

Email address

raziehlotfi@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-20, 1400/02/30

Expected recruitment end date

2021-07-21, 1400/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of virtual based cognitive-behavioral sexual counseling on sexual function, satisfaction and intimacy in pregnant women

Public title

The effect of sexual counseling on sexual function in pregnant women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Sexual function score less than 28 First pregnancy Single pregnancy Wanted pregnancy Gestational age 16 to 24 weeks Low risk pregnancy Having access to a phone with Android operating system Internet literacy Age 18 to 35 years No grief in the three months before the study Living with a spouse

Exclusion criteria:

High risk pregnancies such as placenta previa, threatened miscarriage, gestational hypertension, gestational diabetes and high risk screening Smoking and drinking alcohol Use of drugs and drugs that affect sexual response Sexual dysfunction in the spouse Severe mental illness Attend similar treatment sessions for the past six months

AgeFrom **18 years** old to **35 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **80****Randomization (investigator's opinion)**

Randomized

Randomization description

Block randomization method is used in the present study. This will be done using a random block internet tool via <http://www.sealedenvelope.com/simple-randomiser/v1/lists>. Block size is determined 4 and allocation was done upon arranges of codes in the blocks. Randomization will concealed in sequentially numbered, sealed, opaque envelopes. After producing randomization sequence, 80 opaque envelopes will be provided and each randomization sequence is recorded on a card, then placed in the envelope in order. To keep concealment, envelopes are numbered too. The envelope is sealed and placed in a box in order. At the beginning of the registration of participants, according to the order of entry of eligible participants to study, one of the envelopes will be opened and the assigned group of the participant will be determined.

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 Alborz university of medical sciences

Street address

Alborz University of Medical Sciences, Shahrake Edari, North Taleghani, Azimieh, Karaj

City

Karaj

Province

Alborz

Postal code

3149779453

Approval date

2021-04-26, 1400/02/06

Ethics committee reference number

IR.ABZUMS.REC.1400.023

Health conditions studied**1****Description of health condition studied**

Pregnancy

ICD-10 code

Z70.0

ICD-10 code description

Counseling related to sexual attitude

Primary outcomes**1****Description**

Sexual function score in Rosen's female sexual performance questionnaire

Timepoint

In two turns, before the study begins and four weeks after the end of intervention

Method of measurement

Rosen women's sexual function questionnaire

Secondary outcomes**1****Description**

Sexual satisfaction score in the Larson questionnaire

Timepoint
At the beginning of the study and four weeks the end of the study

Method of measurement
Larson sexual satisfaction questionnaire

2

Description
Sexual intimacy score in the in the Botlani questionnaire

Timepoint
At the beginning of the study and four weeks after the end of the study

Method of measurement
Botlani sexual intimacy questionnaire

Intervention groups

1

Description
Intervention group: Eight weekly 90-minute group sex counseling sessions with virtual content based on cognitive behavioral therapy. First, a group will be formed in one of the messaging systems and research samples will be added to it. The studied samples will be included in the Telegram group. The intervention group will then be divided into three groups to participate in Skyroom classes. A 90-minute session is held weekly for each group. The content of the sessions will be prepared by preparing educational PowerPoint, Weiss, and educational video according to the layout designed in the session table in cooperation with and under the supervision of supervisors and counselors who are sufficiently proficient in sexual issues and sexual cognitive-behavioral counseling. Practice and homework on the taught material will be given at the end of the sessions and in the next sessions the homework will be reviewed. The content of all meetings will be recorded and will be uploaded to the Telegram channel for future reviewed and study for absents. The questions and problems of the samples will be answered individually by the researcher. Depending on the content of each session, text, audio, video or online classes will be used. Content of training sessions including: introduction and familiarity with treatment methods, anatomy and physiology, sexual cycle of men and women-Review and explanation of areas of sexual function and its changes during pregnancy, training and practice of emotions and behavior and training in relaxation, study of emotions, thoughts and sexuality dysfunctional behavior during pregnancy-cognitive errors, explaining the pattern of sexual changes during pregnancy, Practicing sexual fantasies-Rational alternatives, description of different position of intimacy during pregnancy, relaxation exercises and Kegel-exercises to change dysfunctional sexual thoughts, Definition of intimacy and its dimensions, Teaching how to establish intimacy, factors affecting sexual satisfaction and concentration, effective communication and greater participation-Review of teaching sexual relations techniques and answering

questions.

Category
Behavior

2

Description
Control group: 40 pregnant women just receive routine prenatal care

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Fajr Health Center

Full name of responsible person
Manizheh Fathalian

Street address
Milad 1 Alley, Emam Khomeini Street

City
Kamalshahr

Province
Alborz

Postal code
3149779453

Phone
+98 26 3470 3204

Fax

Email
mahtab.fathi358@gmail.com

Web page address

2

Recruitment center

Name of recruitment center
Valiasr Health Center

Full name of responsible person
Manizheh Fathalian

Street address
Meysam 2, Khoramdasht Town

City
Karaj

Province
Alborz

Postal code
3149779453

Phone
+98 26 3480 5863

Email
mahtab.fathi358@gmail.com

Web page address

3

Recruitment center

Name of recruitment center
Amuzgar Health Center 1

Full name of responsible person

Manizheh Fathalian

Street address

No 7, Khazeni Alley, Emamreza Street

City

Karaj

Province

Alborz

Postal code

3149779453

Phone

+98 26 3730 7590

Email

mahtab.fathi358@gmail.com

4

Recruitment center

Name of recruitment center

Golzar Health Center 2

Full name of responsible person

Manizheh Fathalian

Street address

Golzar gharbi Street, 45 metri Golshahr

City

Karaj

Province

Alborz

Postal code

3149779453

Phone

+98 26 3351 5758

Email

mahtab.fathi358@gmail.com

5

Recruitment center

Name of recruitment center

Aadl Health Center 2

Full name of responsible person

Manizheh Fathalian

Street address

No 511, Bahar Building, Emamhosein Square, Shahin vila

City

Karaj

Province

Alborz

Postal code

3149779453

Phone

+98 26 3453 1814

Email

mahtab.fathi358@gmail.com

6

Recruitment center

Name of recruitment center

Zafar Health Center 1

Full name of responsible person

Manizheh Fathalian

Street address

Miad 26, Emamkhomeini Street, Kamalshahr

City

Karaj

Province

Alborz

Postal code

3149779453

Phone

+98 26 3470 1408

Email

mahtab.fathi358@gmail.com

7

Recruitment center

Name of recruitment center

Valad abad bozorg Health Center 2

Full name of responsible person

Manizheh Fathalian

Street address

Roberoye Chamran 1, Emamkhomeini Boulvar, Mohamad shahr

City

Karaj

Province

Alborz

Postal code

3149779453

Phone

+98 26 3631 3437

Email

mahtab.fathi358@gmail.com

8

Recruitment center

Name of recruitment center

Anbari Health Center

Full name of responsible person

Manizheh Fathalian

Street address

Kianpoor Street, Mesbah Street, Emamzadehhasan Boulvar

City

Karaj

Province

Alborz

Postal code

3149779453

Phone

+98 26 3280 4070

Email

mahtab.fathi358@gmail.com

9

Recruitment center

Name of recruitment center

Aghtapeh Health Center

Full name of responsible person

Manizheh Fathalian

Street address

Valiasr Street, Panjome shatghi Street, Eram Boulvar,

Mehrshahr
City
 Mehrshahr
Province
 Alborz
Postal code
 314779453
Phone
 +98 26 3330 9001
Fax
Email
 mahtab.fathi358@gmail.com

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

10

Recruitment center

Name of recruitment center
 Comprehensive Health Center of Hesarak
Full name of responsible person
 Manizheh Fathalian
Street address
 Shahid Khorasani Street, Shahid Beheshti Street
City
 Karaj
Province
 Alborz
Postal code
 314779453
Phone
 +98 26 3456 5667
Email
 mahtab.fathi358@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
 Vice chancellor for research Alborz University of Medical Sciences
Full name of responsible person
 Dr. Mohammad Noorisepehr
Street address
 North Taleghani Street, Azimieh, Karaj
City
 Karaj
Province
 Alborz
Postal code
 3198764653
Phone
 +98 26 3464 4255
Email
 dr.noorisepehr@abzums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research Alborz University of Medical

Person responsible for general inquiries

Contact

Name of organization / entity
 Karaj University of Medical Sciences
Full name of responsible person
 Manizheh Fathalian
Position
 BsC in Midwifery
Latest degree
 Bachelor
Other areas of specialty/work
 Midwifery
Street address
 School of Medicine, University of Medical Sciences
 Campus, University of Art, End of West Bou Ali Street,
 Nobovvat Square, Karaj
City
 Karaj
Province
 Alborz
Postal code
 3149779453
Phone
 +98 26 3419 7685
Email
 mahtab.fathi358@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
 Karaj University of Medical Sciences
Full name of responsible person
 Razieh Lotfi
Position
 Associate Professor
Latest degree
 Ph.D.
Other areas of specialty/work
 Midwifery
Street address
 1st Golestan Street, South Eshteraki Boulevard,
 Baghestan, Karaj
City
 Karaj
Province
 Alborz

Postal code
3149779453
Phone
+98 912 765 5855
Email
Lotfi_razieh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Manizheh Fathalian
Position
BCs in midwifery
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
School of Medicine, University of Medical Sciences
Campus, University of Art, End of West Bou Ali Street,
Nobovvat Square, Karaj
City
Karaj
Province
Alborz
Postal code
3149779453
Phone
+98 26 3419 7685
Email
mahtab.fathi358@gmail.com

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

Not applicable

Analytic Code

Yes - There is 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

Total potential data can be shared after unidentifiable people

When the data will become available and for how long

Data will be in access 6 months after publishing the results

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

Scientific studies

From where data/document is obtainable

Using Email Address: marmarmzf@gmail.com

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

Up to a week after sending the email address

Comments