

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Investigating the effect of sexual counseling based on online problem solving on anxiety and sexual intimacy in women with recurrent pregnancy loss

Protocol summary

Study aim

Comparison of the effect of online problem-solving-based sexual counseling on anxiety and sexual intimacy in women with recurrent pregnancy loss

Design

A experimental study is conducted using a parallel clinical trial method with two parallel groups (each group of 35 people) randomized without blinding on the anxiety and sexual intimacy of 70 qualified women. Sampling is done by simple random allocation method using randomization site.

Settings and conduct

In the recurrent pregnancy loss clinic of Yazd Reproductive Medicine Research Institute, invitation to study, sample selection, random allocation and psychological intervention are carried out by the second researcher under the supervision of the first, third and fourth researchers.

Participants/Inclusion and exclusion criteria

Having a history of at least two recurrent pregnancy loss
Women aged 18-45 years
Not having major stress such as divorce and death of relatives in the last 3 months
Having a cellphone and access to the ITA internal messaging network
Being Iranian; pregnancy patient's or her spouse's affliction with serious psychological disorders such as severe depression and psychosis, consumption of any drug affecting sexual relations by the patient or her spouse (self-reported), history of participating in sexual health education and counseling sessions

Intervention groups

For the intervention group, 8 training sessions will be held online using voice and the possibility of questions and answers with private chat in the internal messaging network of ITA based on the developed program, and the control group will have the same sessions in the form of pamphlets and the possibility of questions and They will

receive an answer with a phone call

Main outcome variables

Change in mean scores of anxiety and sexual intimacy

General information

Reason for update

The intervention is finish. Hello. Two minor items were edited to match the intervention performed.

Acronym

IRCT registration information

IRCT registration number: **IRCT20220620055229N1**

Registration date: **2023-02-14, 1401/11/25**

Registration timing: **prospective**

Last update: **2024-04-10, 1403/01/22**

Update count: **2**

Registration date

2023-02-14, 1401/11/25

Registrant information

Name

Shahla Mohammadkhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3724 0171

Email address

sh.mohamadkhani76@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-04, 1401/11/15

Expected recruitment end date

2023-04-27, 1402/02/07

Actual recruitment start date

2023-03-06, 1401/12/15

Actual recruitment end date

2023-08-06, 1402/05/15

Trial completion date

2023-08-11, 1402/05/20

Scientific title

Investigating the effect of sexual counseling based on online problem solving on anxiety and sexual intimacy in women with recurrent pregnancy loss

Public title

Investigating sexual counseling based on online problem solving on anxiety and sexual intimacy in women with recurrent pregnancy loss

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Having a history of at least two recurrent pregnancy loss
Women aged 18-45 years
Not having major stress such as divorce and death of relatives in the last 3 months
Having a Cellphone and access to ITA's internal messenger network
Being Iranian

Exclusion criteria:

Pregnancy patient's or her spouse's affliction with serious psychological disorders such as severe depression and psychosis
consumption of any drug affecting sexual relations by the patient or her spouse (self-reported)
history of participating in sexual health education and counseling sessions

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Actual sample size reached: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The first-generation random allocation method was used to assign the eligible participants into two intervention and active control groups, each participant was given a number from 1 to 70. Then, using the website <http://www.randomization.com>, participants were randomly assigned into two blocks of 35, C and D. A person external to the study used a random lottery method to select each block as an intervention or active 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**

Research Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Yazd, Bahnar Ave

City

Yazd

Province

Yazd

Postal code

8916189165

Approval date

2023-01-24, 1401/11/04

Ethics committee reference number

IR.SSU.REC.1401.067

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

Sexual dysfunction counseling

ICD-10 code

N96

ICD-10 code description

Recurrent pregnancy loss

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

Change in mean sexual anxiety scores

Timepoint

Baseline, end of intervention in week 8 and end of intervention in week 12

Method of measurement

Sexual anxiety Index (Davis et al.)

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

Change in mean sexual intimacy scores

Timepoint

Baseline, end of intervention in week 8 and end of intervention in week 12

Method of measurement

Sexual Intimacy Index (Bagarouzi et al.)

Intervention groups

1

Description

Intervention group: For the intervention group, 8 training sessions will be held online using voice and the possibility of questions and answers with private chat on the internal messaging network of ITA based on the program developed by the second researcher and under the supervision of the first and third researchers. The content of the sessions includes: explanations about the terms sexual anxiety, sexual intimacy, frequent abortion and problem solving approach, teaching logical problem solving and defining the problem clearly and objectively, setting achievable and realistic goals to solve the problem, learning functional ABCs, training Effective problem solving in real life is through combining emotions and logical thinking, choosing the best solution, evaluating and reviewing. At the beginning of each session, a summary of the previous sessions will be reviewed and the assigned tasks related to the previous session will be reviewed by the researcher. they turn Women are asked to participate in discussions and raise their questions. At the end of each session, a summary of the important topics discussed is presented and people's questions are answered, and women are asked to do their homework in the next sessions.

Category

Behavior

2

Description

Control group: The control group will receive 8 sessions of problem solving advice in the form of pamphlets and the possibility of questions and answers by telephone. The content of the sessions includes explanations about the terms sexual anxiety, sexual intimacy, frequent abortion and problem solving approach, teaching logical problem solving and defining the problem clearly and objectively, setting achievable and realistic goals to solve the problem, learning functional ABCs, Teaching effective real-life problem solving through combining emotions and logical thinking, choosing the best solution, evaluating and revising

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Reproductive Medicine Research Institute of Yazd
repeated abortion clinic

Full name of responsible person

mahshid bokaie

Street address

Bu Ali Ave

City

yazd

Province

Yazd

Postal code

8916877443

Phone

+98 35 3824 7085

Email

mah-bokaie@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr Alireza Moradi

Street address

Yazd, Dr. Bahnar Ave, Central Organization of Shahid
Sadoughi University of Medical Sciences, Yazd

City

Yazd

Province

Yazd

Postal code

8916978477

Phone

+98 35 2637 3337

Fax

+98 35 2637 3237

Email

alirezampr@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

professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Yazd, Bu Ali Ave

City

Yazd

Province

Yazd

Postal code

8916877443

Phone

+98 35 2438 5117

Email

mah-bokaie@yahoo.com

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Bu Ali Ave

City

yazd

Province

Yazd

Postal code

8916877443

Phone

+98 35 2438 5117

Email

mah-bokaie@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

mahshid bokaie

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Yazd, Bu Ali Ave

City

Yazd

Province

Yazd

Postal code

8916877443

Phone

+98 35 2438 5117

Email

mah-bokaie@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

mahshid bokaie

Position

professor

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 personal data of participants can be shared after de-identification.

When the data will become available and for how long

After printing the results

To whom data/document is available

The data will be available for researchers working in academic and scientific institutions, and people working in the industry can apply to receive them.

Under which criteria data/document could be used

Scientific use

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