Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Oct 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 pergnancy 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)

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+98 35 3724 0171

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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

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yazd

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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

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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
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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
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