

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Comparison of the effect of online narrative therapy and routine care on the genital self-image of infertile women.

Protocol summary

Study aim

Determining the effect of online narrative therapy on the mental image of the reproductive system in infertile women

Design

A randomized controlled trial of phase 3 on 64 infertile women. Excel software rand function was used for randomization.

Settings and conduct

First, a list of infertile women will extract from the gynecologist's and family physician's offices. At this stage, a checklist containing the inclusion and exclusion criteria will be prepared and a telephone call will be made to the first person from the extracted list. In case of compliance with the initial checklist and consent to participate in the project, her name will be registered in a list and the rest of the steps will be implemented. These steps will apply to everyone on the list. Next, the Genital self image will determine in these women. Then, those who have a negative Genital self image and have a score less than 23 on the Goldberg General Health Scale will include (subjects who have a score of 23 or higher refer to a psychiatrist), and finally 64 people who are eligible, after obtaining informed consent to participate in the research, enter the study. Finally, these subjects will allocate into two groups of 32 people by blocked randomization method.

Participants/Inclusion and exclusion criteria

Iranian women between the ages of 18 and 40 who are literate and live with their husbands and did not become pregnant after a year of regular and unprotected intimacy. Willing to participate in the study.

Intervention groups

In the intervention group, five 90-minute sessions in groups, the narrative therapy counseling package will be performed online. The control group will also receive routine care, and after the intervention, a narrative therapy educational pamphlet will be provided to the control group, and a session will be held to answer any

questions.

Main outcome variables

Genital self-image

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161126031117N11**

Registration date: **2021-11-15, 1400/08/24**

Registration timing: **prospective**

Last update: **2021-11-15, 1400/08/24**

Update count: **0**

Registration date

2021-11-15, 1400/08/24

Registrant information

Name

Soghra Khani

Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-30, 1400/09/09

Expected recruitment end date

2022-02-28, 1400/12/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of online narrative therapy and routine care on the genital self-image of infertile women.

Public title

The effect of online narrative therapy on the genital self-image of infertile women. A randomized controlled clinical trial study

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Being Iranian Having literacy and literacy Speaking Persian Having an age between 18-49 years Having Primary infertility for more than one year confirmed by a gynecologist and infertility specialist Having a smart phone and internet getting a registered marriage Having a written consent to participate in the research Being generally healthy based on the Goldberg General Health Questionnaire

Exclusion criteria:

Couples' addiction to drugs and alcohol The occurrence of a stressful accident in the past six months Use of drugs affecting sexual function Having obvious physical disabilities and Mentally affecting sexual function History of pelvic surgery or radiation to the genitals Having an adopted child

Age

From **18 years** old to **49 years** old

Gender

Female

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **64****Randomization (investigator's opinion)**

Randomized

Randomization description

Blocking method will be used for random assignment of samples to two groups of 32. For this purpose, 16 blocks of four will be considered. The six possible blocks are TTCC TCTC, TCCT, CCTT, CTCT, CTTC, where T is for the intervention group and C is for the control group. The numbers will be generated randomly (with the RANDBETWEEN command in Excel software and in the range 0 to 6) and according to the production values of one of the blocks (for a production number between 0 to 1 CTTC block, for a production number between 1 to 2 blocks CTCT and so on) will be selected and samples will be assigned.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Moallem Square, Vice Chancellor for Research and Technology, Mazandaran University of Medical Sciences

City

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Mazandaran

Postal code

48178-57344

Approval date

2021-10-02, 1400/07/10

Ethics committee reference number

IR.MAZUMS..REC.1400.10428

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

Infertile women with a negative genital self image

ICD-10 code

MB27.3

ICD-10 code description

Disturbance of body image

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

Genital self-image

Timepoint

Before, immediately and 45 days after the intervention

Method of measurement

Genital self-image Scale

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

Sexual satisfaction

Timepoint

Before, immediately and 45 days after the intervention

Method of measurement

Hudson Sexual Satisfaction Questionnaire

Intervention groups

1

Description

Intervention group: In the intervention group, 5 90-minute sessions (1 session per week) as a group, in 4 groups of 7 people and a group of 4 people, narrative therapy counseling package (compilation of therapy package based on the theory of narrative therapy and concepts and principles The theory has been narrative therapy) will be implemented online and using the WhatsApp platform, by a master student in midwifery counseling, which is supervised by a research team including: a reproductive health specialist and a PhD student in clinical psychology. It should be noted that participants prepare their narration in writing (file typed in word or handwritten photo) and send it to the researcher in private message on the WhatsApp platform. The control group will also receive routine care, and after the intervention, a narrative therapy educational pamphlet will be provided to the control group, and a session will be held to answer any questions.

Category

Treatment - Other

2

Description

Control group: The control group will also receive routine care, and after the intervention, a narrative therapy educational pamphlet will be provided to the control group, and a session will be held to answer any questions.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

gynecologist office, Sari health centers and Sari family physicians offices

Full name of responsible person

Dr Aghil Barzegar

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Amir Mazandarani St. - Kargar Square - Sari Health Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Akbar Hedayatzadeh Imran

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Moallem Square - Moallem Street - Research Center of Mazandaran University of Medical Sciences

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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

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Soghara Khani

Position

Associate Professor, Mazandaran University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for scientific inquiries

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Latest degree

Ph.D.

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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

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

Research-related information is shared with the aim of keeping individuals' names and identities confidential and adhering to the 31 Code of Ethics.

When the data will become available and for how long

2022

To whom data/document is available

All researchers and research enthusiasts

Under which criteria data/document could be used

For review and supplementary research and For use by therapists of infertile women

From where data/document is obtainable

If the article is published according to the address of the magazine, you can refer to that magazine. Also, for additional information, you can access the responsible author by e-mail khanisog343@gmail.com and the e-mail of the midwifery student by e-mail fateme.shahriari.midwife@gmail.com.

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

She /He must first send an email to the author of the article and submit her request, and if the author and the research team deem it appropriate, the documents and files will be provided in a short time.

Comments