

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparison of the efficacy Cognitive Behavioral Therapy, Biofeedback and combination of Cognitive Behavioral Therapy and Biofeedback On the treatment of vaginismus

Protocol summary

Study aim

Comparison of the efficacy Cognitive Behavioral Therapy, Biofeedback and combination of Cognitive Behavioral Therapy and Biofeedback On the treatment of vaginismus

Design

Number of 30 patients with Vaginismus Disorder were selected by purposeful sampling and then randomly divided into three groups in parallel with cognitive-behavioral intervention, biofeedback and combination of cognitive-behavioral therapy and biofeedback in equal parts.

Settings and conduct

Individuals of all three groups of cognitive-behavioral intervention, biofeedback and combination of cognitive-behavioral therapy and biofeedback received the first diagnosis of vaginismus on the basis of DSM-5 before the relevant interventions in the psychiatric clinic and then completed the FSFI questionnaire. After the end of the interventions, the questionnaire will again be available to the members to complete them and the level of effectiveness will be checked.

Participants/Inclusion and exclusion criteria

Entry criteria: Suffering of Type I vaginismus (unconsummated marriage) Initial diagnosis of vaginismus based on DSM-5 Having normal cognitive levels Having at least a cycle education Get a score of 35-63 based on The Female Sexual Function Index (FSFI)
Non-entry criteria: Patients with vaginismus physical conditions based on gynecologic examination Pregnancy Ovarian tumor (vagina, Cervical and uterus) The presence of major medical or psychiatric illnesses Receiving psychiatric treatments at the time of study Reception history of cognitive-behavioral training

Intervention groups

There are three intervention groups in this study. A group Receive cognitive-behavioral therapy, the second

group biofeedback and the third group combination of cognitive-behavioral therapy and biofeedback.

Main outcome variables

Vaginismus, cognitive-behavioral therapy And biofeedback

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190427043391N1**

Registration date: **2019-05-06, 1398/02/16**

Registration timing: **retrospective**

Last update: **2019-05-06, 1398/02/16**

Update count: **0**

Registration date

2019-05-06, 1398/02/16

Registrant information

Name

Alireza Eivazi

Name of organization / entity

University of Applied Sciences Red Crescent Gilan

Country

Iran (Islamic Republic of)

Phone

+98 13 4223 0063

Email address

eivazi_ar@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-14, 1397/01/25

Expected recruitment end date

2018-08-28, 1397/06/06
Actual recruitment start date
 2018-06-02, 1397/03/12
Actual recruitment end date
 2018-11-14, 1397/08/23
Trial completion date
 2019-03-06, 1397/12/15

Scientific title
 Comparison of the efficacy Cognitive Behavioral Therapy, Biofeedback and combination of Cognitive Behavioral Therapy and Biofeedback On the treatment of vaginismus

Public title
 The efficacy of Cognitive Behavioral Therapy and Biofeedback On the treatment of vaginismus

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Suffering of Type I vaginismus (unconsummated marriage) Initial diagnosis of vaginismus based on DSM-5 Having normal cognitive levels Having at least a cycle education Get a score of 35-63 based on The Female Sexual Function Index (FSFI)
Exclusion criteria:
 Patients with vaginismus physical conditions based on gynecologic examination Pregnancy Ovarian tumor (vagina, Cervical and uterus) The presence of major medical or psychiatric illnesses Receiving psychiatric treatments at the time of study Reception history of cognitive-behavioral training

Age
 From **19 years** old to **35 years** old

Gender
 Female

Phase
 N/A

Groups that have been masked

- Participant

Sample size
 Target sample size: **30**
 Actual sample size reached: **30**

Randomization (investigator's opinion)
 Not randomized

Randomization description

Blinding (investigator's opinion)
 Single blinded

Blinding description
 Participants in three groups of cognitive-behavioral therapy, biofeedback and the combination of cognitive-behavioral therapy and biofeedback have not information on the type of intervention of other people in their group and other groups.

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gilan University of Medical Sciences

Street address

In front of the hospital 17 Shahrivar, Shahid Siadati Street, Namjoo Street

City

Rasht

Province

Guilan

Postal code

4144666949

Approval date

2018-02-21, 1396/12/02

Ethics committee reference number

IR.GUMS.REC.1396.472

Health conditions studied

1

Description of health condition studied

Vaginismus Disorder

ICD-10 code

F52.6

ICD-10 code description

Dyspareunia not due to a substance or known physiological condition

Primary outcomes

1

Description

Intercourse

Timepoint

At the end of the intervention

Method of measurement

Person report

Secondary outcomes

1

Description

Desire

Timepoint

The beginning of the study (before the intervention) and after the intervention

Method of measurement

The Female Sexual Function Index

2

Description

Arousal

Timepoint

The beginning of the study (before the intervention) and after the intervention

Method of measurement

The Female Sexual Function Index

3

Description

Lubrication

Timepoint

The beginning of the study (before the intervention) and after the intervention

Method of measurement

The Female Sexual Function Index

4

Description

Orgasm

Timepoint

The beginning of the study (before the intervention) and after the intervention

Method of measurement

The Female Sexual Function Index

5

Description

Satisfaction

Timepoint

The beginning of the study (before the intervention) and after the intervention

Method of measurement

The Female Sexual Function Index

6

Description

Pain

Timepoint

The beginning of the study (before the intervention) and after the intervention

Method of measurement

The Female Sexual Function Index

Intervention groups

1

Description

Intervention group1: Cognitive-behavioral intervention consists of 10 sessions of 45-minute therapy. A major part of the Therapeutic Plan is the creation of a therapeutic relationship, the teaching of body anatomy, identifying and challenging with illogical and negative beliefs associated with sexuality, the teaching of Relaxation and Diaphragmatic breathing, and sexual imagination with it and their practice at home as a

homework.

Category

Behavior

2

Description

Intervention group 2: Biofeedback intervention consists of 10 sessions of 45-minute therapy. The therapeutic protocol includes an explanation of the biofeedback treatment process, diaphragmatic breathing training and relaxation, surface massage and tensile movements of the edenturer; determining and recording the threshold of vaginal muscle contraction on the diagram on the monitor surface and attempting to reduce the contraction threshold by relaxing the pelvic floor muscles Gradually during the sessions to reach the bottom of the threshold; the use of superficial biofeedback on Eddator's muscles and gradually advancing the patient's finger and his wife (at home) as a dilator and practicing at home.

Category

Treatment - Devices

3

Description

Intervention group 3: Cognitive-behavioral and biofeedback combined intervention includes 10 sessions of 45-minute therapy. The therapeutic protocol includes the creation of a therapeutic relationship, the teaching of body anatomy, identifying and challenging with illogical and negative beliefs associated with sexuality, explanation of the biofeedback treatment process, diaphragmatic breathing training and relaxation, surface massage and tensile movements of the edenturer; determining and recording the threshold of vaginal muscle contraction on the diagram on the monitor surface and attempting to reduce the contraction threshold by relaxing the pelvic floor muscles Gradually during the sessions to reach the bottom of the threshold; the use of superficial biofeedback on Eddator's muscles and gradually advancing the patient's finger and his wife (at home) as a dilator and practicing at home.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialist Consulting Center And Mental Health of Dr. Eyvazi

Full name of responsible person

Alireza Eivazi

Street address

Dr. Eyvazi's Clinic, Tavakoli alley, Shahid Karimi Avenue, Martyrs' Square

City

Lahijan

Province

Guilan
Postal code
4418693814
Phone
+98 13 4223 0063
Email
Eivazi_ar@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Shadman Nemati
Street address
In front of the hospital 17 Shahrivar, Shahid Siadati
Street, Namjoo Street
City
Rasht
Province
Guilan
Postal code
4144666949
Phone
+98 13 3333 5820
Email
nemati@gums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht 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
University of Applied Sciences Red Crescent Gilan
Full name of responsible person
Alireza Eivazi
Position
Psychiatrist
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics

Street address

The office dr Eivazi, Alley Tavakoli, West Karimi,
Square Shohada, Lahijan Town

City

Lahijan

Province

Guilan

Postal code

4418693814

Phone

+98 13 4223 0063

Fax

Email

Eivazi_ar@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of Applied Sciences Red Crescent Gilan
Full name of responsible person
Alireza Eivazi
Position
Psychiatrist
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
The office dr Eivazi, Alley Tavakoli, West Karimi,
Square Shohada, Lahijan Town
City
Lahijan
Province
Guilan
Postal code
4418693814
Phone
+98 13 4223 0063
Fax
Email
Eivazi_ar@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
University of Applied Sciences Red Crescent Gilan
Full name of responsible person
Alireza Eivazi
Position
Psychiatrist
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
The office dr Eivazi, Alley Tavakoli, West Karimi,
Square Shohada, Lahijan Town
City
Lahijan

Province

Guilan

Postal code

4418693814

Phone

+98 13 4223 0063

Fax**Email**

Eivazi_ar@yahoo.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available