

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The impact of Cognitive Behavioral Sex Therapy for Vaginismus (CBST-V) on decreasing anxiety and increasing sexual function

Protocol summary

Summary

Purpose: This study have been designed to evaluate the effect of Cognitive Behavioral Sex Therapy for Vaginismus on decreasing anxiety and increasing sexual function in patients with vaginismus. Method: Statistical population included all married women aged 20-35 years old with vaginismus. That referred to Farhangian Shahid Abuzari and Vali-Asr therapeutic centers in Shahr-e-Ray city. According to inclusion criteria, thirty women with vaginismus were selected as study sample and randomly assigned to two control and experimental groups. Research design was pretest-posttest with a control group. The experimental groups were trained in cognitive behavioral sex therapy for vaginismus during twelve sessions, on hour in each week. The Female Sexual Function Index (2000) and State-Trait Anxiety Inventory (1983) were used as instruments of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016031027004N1**

Registration date: **2016-11-29, 1395/09/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-29, 1395/09/09

Registrant information

Name

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Name of organization / entity

Payame Noor University

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Recruitment status

Recruitment complete

Funding source

Payame Noor University

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-01-19, 1395/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of Cognitive Behavioral Sex Therapy for Vaginismus (CBST-V) on decreasing anxiety and increasing sexual function

Public title

The therapeutic and educational package for sexual disorders of women

Purpose

Treatment

Inclusion/Exclusion criteria

Criteria for inclusion: age between 20-35 years old; Diagnosis of vaginismus by a gynecologist. Criteria for exclusion: having female sexual problems and severe inflammatory diseases of genital system; Severe psychological disorders

Age

From **20 years** old to **35 years** old

Gender

Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 30

Randomization (investigator's opinion)
Randomized

Randomization description

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
Mazandaran University of Medical Sciences

Street address
Sari, Imam Square

City
Sari

Postal code

Approval date
2016-10-19, 1395/07/28

Ethics committee reference number
IR.MAZUMS.REC.95.S173

Health conditions studied

1

Description of health condition studied
Vaginismus

ICD-10 code
N94.2

ICD-10 code description
Spasm of the pelvic floor muscles that surround the vagina, causing occlusion of the vaginal opening. Penile entry is either impossible or painful.

Primary outcomes

1

Description
anxiety

Timepoint
Before the intervention and 3 months after the intervention

Method of measurement

Questionnaires of The State-Trait Anxiety Inventory (Spielberger, 1983)

2

Description
Sexual Function

Timepoint
Before the intervention and 3 months after the intervention

Method of measurement
Female Sexual Function Index (Rosen et al, 2000)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This therapeutic package has been made based on the cultural-related features and the differences which exist among Iranian women as compared with Western women. Its underlying principles were taken from the instructions of Ter Kuile et al. (2007), Their study was done on patients with vaginismus. Therefore, additional cases was necessary that were reviewed and approved by a number of psychologists and gynecologists. This training designed for twelve weeks, a one-hour session in each week. A summary of the Cognitive Behavioral Sex Therapy for Vaginismus package was as follows: 1) Becoming familiar with the female sexual disorders and cognitive-behavioral therapy, 2) Defining normal sexual orientation and physiological responses and describing male and female's sexual cycles, 3) Muscle relaxation training, 4) Effective communication training, 5) Problem solving, self-confidence reinforcement and anger management skills training, 6) Cognitive restructuring in relation to sexual-mental disorders, 8) Improving sexual techniques and skills (sensory focus 1), 9) Improving sexual techniques and skills (sensory focus 2), 10,11,12) Regular desensitization for sexual penetration. Each of the main topics of this educational package was instructed in one or two sessions and in all sessions some assignment were given to participants. This educational package is not only usable for women with vaginismus and other sexual problems, but also its instructions can be used for all women who want to improve their sexual functioning, even if they do not have any sexual problems.

Category
Behavior

2

Description
For the control group, no intervention was done. In case of proving the hypotheses, this treatment will be taught the control group for free.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Farhangian Shahid Abuzari Therapeutic center

Full name of responsible person

A'zam Mohammadi

Street address

City

Shahr-e-Ray

2

Recruitment center

Name of recruitment center

Vali-Asr Therapeutic Center

Full name of responsible person

A'zam Mohammadi

Street address

City

Shahr-e-Ray

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Payame Noor University

Full name of responsible person

Mahnaz Aliakbari Dehkordi

Street address

Nejatollahi st., Enghelab Avenue

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Payame Noor University

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Payame Noor University

Full name of responsible person

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Position

Psychology, MSc

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty