Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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

Behavior

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
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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