

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effectiveness of cognitive behavioral therapy on sexual shyness, sexual daring and sexual performance in women with vaginismus

Protocol summary

Study aim

The purpose of this study is the effectiveness of cognitive behavioral therapy on sexual shyness, sexual daring and sexual performance in women with vaginismus.

Design

Semi-experimental study with multiple baseline method, without control group, without blinding, randomly on 3 patients

Settings and conduct

Screening to find samples is done in sexual disorders treatment clinics and private offices in Ahvaz city, and counseling is done by the researcher at Binish Counseling Center in Ahvaz city. To implement the treatment method, the first person enters the treatment plan, and at each stage of the baseline, the research tools (Female Sexual Function Index- Hullbert Index of Sexual Desire- Sexual Self-Consciousness Index) are implemented on the first person. The first person is measured twice, the second person three times, the third person four times. Measurements are done weekly by completing the research tools. Then the treatment is carried out by the researcher for 8 weekly sessions of 90 minutes. All questionnaires are completed in sessions 4, 2, 6 and immediately after the treatment. In order to follow up, people are re-evaluated two months after the treatment in three twenty-day sessions.

Participants/Inclusion and exclusion criteria

The criteria for entering the study include: age 18-45 years old - cycle education - confirmation of vaginismus by a psychiatrist, and the exclusion criteria include having a mental illness.

Intervention groups

Cognitive behavioral therapy is performed as 8 sessions of 90 minutes and once a week based on the package "Sexual cognitive behavioral therapy in vaginismus".

Main outcome variables

sexual shyness, sexual daring and sexual performance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220713055457N1**

Registration date: **2022-11-02, 1401/08/11**

Registration timing: **prospective**

Last update: **2022-11-02, 1401/08/11**

Update count: **0**

Registration date

2022-11-02, 1401/08/11

Registrant information

Name

Zohreh Ahmady

Name of organization / entity

Islamic Azad University Behbahan Branch

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-06, 1401/08/15

Expected recruitment end date

2022-11-13, 1401/08/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of cognitive behavioral therapy on sexual shyness, sexual daring and sexual performance in women with vaginismus

Public title

The effectiveness of cognitive behavioral therapy on sexual shyness, sexual daring and sexual performance in women with vaginismus

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-45 years Confirmation of vaginismus by a psychiatrist Cycle education

Exclusion criteria:

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: **3**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University
Behbahan Branch

Street address

Shahid Bayani Ave., AmirKabir Blvd., Behbahan City

City

Behbahan

Province

Khouzestan

Postal code

6361713198

Approval date

2022-09-19, 1401/06/28

Ethics committee reference number

IR.IAU.BEHBAHAN.REC.1401.019

Health conditions studied

1

Description of health condition studied

vaginismus

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

sexual performance in women with vaginismus

Timepoint

Examination of sexual performance before the study - sessions 4, 2, 6, immediately after completion of treatment and two months after treatment

Method of measurement

Female Sexual Function Index- Hullbert Index of Sexual Desire- Sexual Self-Consciousness Index

2

Description

sexual shyness in women with vaginismus

Timepoint

Examination of sexual shyness before the study - sessions 4, 2, 6, immediately after completion of treatment and two months after treatment

Method of measurement

Female Sexual Function Index- Hullbert Index of Sexual Desire- Sexual Self-Consciousness Index

3

Description

sexual daring in women with vaginismus

Timepoint

Examination of sexual daring before the study - sessions 4, 2, 6, immediately after completion of treatment and two months after treatment

Method of measurement

Female Sexual Function Index- Hullbert Index of Sexual Desire- Sexual Self-Consciousness Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: consists of 3 women. cognitive behavioral therapy is performed by the researcher for 8 weekly sessions of 90 minutes.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Binesh Consulting Center

Full name of responsible person

Leyla Jazayeri

Street address

No. 20, West 7th Street, Kianpars Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Shahrooei

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Zohreh Ahmady

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Person responsible for updating data

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable