

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jul 2026

### Effect of virtual based cognitive behavioral therapy of vaginism in Iranian women: a randomized controlled clinical trial

#### Protocol summary

##### Study aim

Effect of virtual based cognitive behavioral therapy of vaginism in Iranian women: RCT

##### Design

The study will be performed on 40 women with primary vaginism aged 18-40 years who refer to sexual dysfunction treatment centers. Block randomization is used for randomization using Internet tools.

##### Settings and conduct

Sampling will be performed among women with primary vaginism aged 18-40 years who refer to treatment centers for sexual disorders and with an initial diagnosis by a team's sexologist. Sampling will be available in such a way that the researcher uses the telephone number in the file of eligible people and after giving explanations about the objectives and how to conduct the research, invites them to a specific time to complete the questionnaires. For random allocation, block randomization by Internet tools will be used.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of vaginismus based on DSM-5 by a sexologist Marital status and living with a spouse Age: 18-40 years No pregnancy Be literate Using the Internet to communicate educational counselingve sufficient Persian skills in reading and writing Have sufficient Persian skills in reading and writing Exclusion criteria: Psychosis or Dissociative symptoms in the past or present Post Traumatic Stress Disorder(PTSD) Traumatization due tosexual abuse in the past or the present Substance abuse or dependency in the present Moderate or severe depressionor bipolar disorder in the present Currently being treated for vaginismus Patients with physical causes leading to vaginismus Sexual dysfunction in partner Pregnancy Death of a spouse Divorce People who have not participated in the study for 2 sessions or more

##### Intervention groups

Women with primary vaginism aged 18-40 years referred to sex disorder treatment centers

#### Main outcome variables

vaginal penetration

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20161230031662N11**

Registration date: **2021-08-29, 1400/06/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-08-29, 1400/06/07**

Update count: **0**

##### Registration date

2021-08-29, 1400/06/07

##### Registrant information

##### Name

Razieh Lotfi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3430 4433

##### Email address

raziehlutfi@abzums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-08-06, 1400/05/15

##### Expected recruitment end date

2021-10-07, 1400/07/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Effect of virtual based cognitive behavioral therapy of vaginism in Iranian women: a randomized controlled clinical trial

**Public title**

The effectiveness of virtual based cognitive behavioral therapy in vaginism

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Diagnosis of vaginismus based on DSM-5 by a sexologist  
Marital status and living with a spouse Age: 18-40 years  
No pregnancy Be literate Using the Internet to communicate educational counselingve sufficient Persian skills in reading and writing Have sufficient Persian skills in reading and writing

**Exclusion criteria:**

Psychosis or dissociative symptoms in the past or present Post Traumatic Stress Disorder(PTSD)  
Traumatization due to sexual abuse in the past or the present, Substance abuse or dependency in the present  
Moderate or severe depression or bipolar disorder in the present Currently being treated for vaginismus Patients with physical causes leading to vaginismus Sexual dysfunction in partner Pregnancy Death of a spouse  
Divorce People who have not participated in the study for 2 sessions or more

**Age**From **18 years** old to **40 years** old**Gender**

Female

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **40****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization method is used in the present study. This will be done using a random block internet tool via <http://www.sealedenvelope.com/simple-randomiser/v1/lists>. Block size is determined 4 and allocation was done upon arrangement of codes in the blocks. Randomization will be concealed in sequentially numbered, sealed, opaque envelopes. After producing randomization sequence, 80 opaque envelopes will be provided and each randomization sequence is recorded on a card, then placed in the envelope in order. To keep concealment, envelopes are numbered too. The envelope is sealed and placed in a box in order. At the beginning of the registration of participants, according to the order of entry of eligible participants to study, one of the envelopes will be opened and the assigned group of the participant will be determined.

**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**

Ethics Committee of Alborz university of medical sciences

**Street address**

Alborz University of Medical Sciences, Shahrake Edari, North Taleghani, Azimieh, Karaj

**City**

Alborz

**Province**

Alborz

**Postal code**

3149779453

**Approval date**

2021-08-02, 1400/05/11

**Ethics committee reference number**

IR.ABZUMS.REC.1400.113

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

vaginismus

**ICD-10 code**

Z70

**ICD-10 code description**

Counseling related to sexual attitude, behavior and orientation

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

penetration

**Timepoint**

Before the intervention, immediately after the intervention, 4 weeks after the end of the intervention

**Method of measurement**

Through questionnaires

**Secondary outcomes**

## 1

### Description

Sexual function

### Timepoint

Before the intervention , Immediately after the intervention, 4 weeks after the end of the intervention

### Method of measurement

Rosen's sexual function Questionnaire(FSFI)

## Intervention groups

## 1

### Description

The intervention consists of eight sessions composed of modules for psychoeducation, cognitive restructuring, relaxation exercises, sensate focus, attention-focusing for pain-management, body exposure and self-exploration, desensitization and gradual exposure with fingers or dilators and preparation exercises for sexual intercourse, which will be performed weekly (in some cases twice a week).

### Category

Behavior

## 2

### Description

Control group: No intervention will be taken during this period for the control group.

### Category

N/A

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Kamali Educational and Medical Center

#### Full name of responsible person

Dr.Razieh Lotfi

#### Street address

Shahid Beheshti St. - Shohada Sq. - Kamali St.

#### City

karaj

#### Province

Alborz

#### Postal code

3149969415

#### Phone

+98 26 3222 2021

#### Email

lotfi\_razieh@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

Name of organization / entity

Research Assistant of Alborz University of Medical Sciences

### Full name of responsible person

Dr. Mohammad Noorisepehr

### Street address

North Taleghani Street, Azimieh

### City

karaj

### Province

Alborz

### Postal code

3198764653

### Phone

+98 26 3464 4255

### Email

dr.noorisepehr@abzums.ac.ir

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Research Assistant of Alborz 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

Alborz University of Medical Sciences

#### Full name of responsible person

Maedeh Bina

#### Position

BCs of Midwifery

#### Latest degree

Bachelor

#### Other areas of specialty/work

Midwifery

#### Street address

School of Medicine, University of Medical Sciences Campus, University of Art, End of West Bou Ali Street, Nobovvat Square, Karaj

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karaj

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#### Phone

+98 26 3419 7685

#### Email

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

A;borz University of Medical Sciences

**Full name of responsible person**

Razieh Lotfi

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

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## Person responsible for updating data

### Contact

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Alborz University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

Midwifery

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**Phone**

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**Email**

maedehbina64@gmail.com

## 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**

Total potential data can be shared after unidentifiable people

**When the data will become available and for how long**

Data will be in access 6 months after publishing the results

**To whom data/document is available**

Only for researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

En Scientific studies

**From where data/document is obtainable**

Using Email Address : Lotfi\_razieh@yahoo.com

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

Up to a week after sending the email address

**Comments**