Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
raziehlotfi@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 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

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 arranges of codes in the blocks. Randomization will 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 andl 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.
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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
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Postal code
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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 Midwiery
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Razieh Lotfi

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

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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