

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Efficacy of Cognitive Behavioral Therapy on women with vaginismus: A Replicated Single-Case Study

#### Protocol summary

##### Summary

The present study designed to determine the effect of cognitive behavioral therapy in the treatment of lifelong vaginismus in Ahvaz city. This study was designed in 2015 year. Single-case design was used to investigate the effectiveness exposure for Lifelong vaginismus. The participants were 4 women with vaginismus that completed a questionnaire about demographic and multidimensional vaginal penetration Questionnaire (MVPDQ). The participants function in the pre-intervention stage or baseline used to predict the behavior of participants in future. The treatment for 8 weekly sessions was conducted for each participant on an individual basis. The duration of each session was 45 minutes. In order to follow-up, the participants will evaluate after two month in three times with twenty-day re-evaluation. Inclusion criteria: 1. Lifelong vaginismus (unconsummated marriage) 2. The ability of reading and writing at least 3. Women between 18 to 35 years old Exclusion criteria: 1. Patient with physical causes of vaginismus according to the gynecologist or midwife's diagnosis 2. Acute or chronic physical disease 3. Mental illness confirmed by psychiatric 4. Addiction to drugs or alcohol 5. Have a Partner with any kind of sexual dysfunction

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015110724922N1**

Registration date: **2016-06-20, 1395/03/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-06-20, 1395/03/31

#### Registrant information

##### Name

Arezoo Rezaei KheyrAbady

##### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3373 8091

##### Email address

rezaei.a@ajums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

University of Medical Sciences Ahvaz

#### Expected recruitment start date

2015-06-05, 1394/03/15

#### Expected recruitment end date

2015-07-06, 1394/04/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Efficacy of Cognitive Behavioral Therapy on women with vaginismus: A Replicated Single-Case Study

#### Public title

Efficacy of Cognitive Behavioral Therapy on women with vaginismus

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: 1. Lifelong vaginismus (unconsummated marriage) 2.the ability of reading and writing at least 3.women between 18 to 35 years old exclusion criteria: 1.Patient with physical causes of

vaginismus according to the gynecologist or midwife's diagnosis 2. Acute or chronic physical disease 3. Mental illness confirmed by psychiatric 4. Addiction to drugs or alcohol 5- have a Partner with any kind of sexual dysfunction

#### Age

From **18 years** old to **35 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **4**

#### 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 Ahvaz Jundishapur University of Medical Sciences

##### Street address

Golestan superhighway, Ahvaz city, Khozestan State, Iran

##### City

Ahvaz

##### Postal code

#### Approval date

2015-05-06, 1394/02/16

#### Ethics committee reference number

ir.ajums.rec.1394.181

## Health conditions studied

### 1

#### Description of health condition studied

vaginismus

#### ICD-10 code

N94.2

#### ICD-10 code description

psychogenic vaginismus

## Primary outcomes

### 1

#### Description

penetration

#### Timepoint

End intervention

#### Method of measurement

Report person

## Secondary outcomes

### 1

#### Description

Genital conflict

#### Timepoint

Before intervention, second session, fourth session, sixth session, eighth session, three follow up two months after intervention with twenty day interval

#### Method of measurement

Multi dimensional vaginal penetration Questionnaire

### 2

#### Description

Terrible thoughts and contraction

#### Timepoint

Before intervention, second session, fourth session, sixth session, eighth session, three follow up two months after intervention with twenty day interval

#### Method of measurement

Multi dimensional vaginal penetration Questionnaire

### 3

#### Description

helplessness

#### Timepoint

Before intervention, second session, fourth session, sixth session, eighth session, three follow up two months after intervention with twenty day interval

#### Method of measurement

Multi dimensional vaginal penetration Questionnaire

### 4

#### Description

Marital adjustment

#### Timepoint

Before intervention, second session, fourth session, sixth session, eighth session, three follow up two months after intervention with twenty day interval

#### Method of measurement

Multi dimensional vaginal penetration Questionnaire

### 5

#### Description

Shirk

#### Timepoint

Before intervention, second session, fourth session, sixth

session, eighth session, three follow up two months after intervention with twenty day interval

**Method of measurement**

Multi dimensional vaginal penetration Questionnaire

**6**

**Description**

Impetus

**Timepoint**

Before intervention, second session, fourth session, sixth session, eighth session, three follow up two months after intervention with twenty day interval

**Method of measurement**

Multi dimensional vaginal penetration Questionnaire

**7**

**Description**

Sexual Information

**Timepoint**

Before intervention, second session, fourth session, sixth session, eighth session, three follow up two months after intervention with twenty day interval

**Method of measurement**

Multi dimensional vaginal penetration Questionnaire

**8**

**Description**

hypervigilant

**Timepoint**

Before intervention, second session, fourth session, sixth session, eighth session, three follow up two months after intervention with twenty day interval

**Method of measurement**

Multi dimensional vaginal penetration Questionnaire

**9**

**Description**

optimism

**Timepoint**

Before intervention, second session, fourth session, sixth session, eighth session, three follow up two months after intervention with twenty day interval

**Method of measurement**

Multi dimensional vaginal penetration Questionnaire

**Intervention groups**

**1**

**Description**

The present study is a replicated single-case design which evaluates the effect of CBT for lifelong vaginismus. Participants are 4 women with vaginismus that completed a demographic and multidimensional vaginal penetration Questionnaire (MVPDQ). The pre-intervention baseline performance or stage in participants, is used to predict the behavior of participants in the future. Then, the 8 weekly session's treatment will conduct for each person on an individual basis. The duration of each

session was 45 minutes. In order to follow-up, the participants will evaluate after two month in three times with twenty-day re-evaluation. In each treatment session, anatomy and physiology of male and female genitalia, sexual cycle relaxation methods will be taught. Also we will try to change the attitude, maladaptive thoughts and penetration fear.

**Category**

Behavior

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Binesh Consulting Center

**Full name of responsible person**

Zahra Kakanezhad

**Street address**

Kiyan pars street, Ahvaz city, Khozestan State

**City**

Ahvaz

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor for Research of Ahvaz Jundishapur University of Medical Science

**Full name of responsible person**

Dr. Nader Saki

**Street address**

Golestan Blvd, Ahvaz Jundishapur University of Medical Science

**City**

Ahvaz

**Grant name**

-

**Grant code / Reference number**

-

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

Yes

**Title of funding source**

Vice Chancellor for Research of Ahvaz Jundishapur University of Medical Science

**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**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

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## Person responsible for updating data

### Contact

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## Person responsible for scientific inquiries

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**Fax**

-

## 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*